

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

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

**PULMONX CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

3841  
(Primary Standard Industrial  
Classification Code Number)  
700 Chesapeake Drive  
Redwood City, California 94063  
1-650-364-0400

77-0424412  
(I.R.S. Employer  
Identification Number)

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Glendon E. French  
Chief Executive Officer  
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1-650-364-0400

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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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, as amended, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) 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.

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.

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 number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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**CALCULATION OF REGISTRATION FEE**

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<b>Title of Each Class of Securities To Be Registered</b>	<b>Proposed Maximum Aggregate Offering Price<sup>(1)(2)</sup></b>	<b>Amount of Registration Fee</b>
Common Stock, \$0.001 par value per share	\$	\$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

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**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 that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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**EXPLANATORY NOTE**

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our financial information for the historical 2017 annual period or for any interim period for 2018 or 2019 because we plan to file our financial information for the year ended December 31, 2019 in the first public filing of our registration statement. The 2017 annual financial information and 2018 and 2019 interim financial information relate to historical periods that we believe will not be required to be included in our registration statement at the time of the first public filing. We intend to amend the registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

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 we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion  
Preliminary Prospectus dated \_\_\_\_\_, 2020

**PROSPECTUS**

**Shares**



**Pulmonx Corporation**

**Common Stock**

This is Pulmonx Corporation's initial public offering. We are selling \_\_\_\_\_ shares of our common stock.

We expect the public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. Currently, no public market exists for the shares of our common stock. We have applied to list our common stock on the Nasdaq Global Market under the symbol "PMNX."

We are an "emerging growth company" as defined under the U.S. federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements for this and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

**Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 11 of this prospectus.**

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ _____	\$ _____
Underwriting discount(1)	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) See "Underwriting" beginning on page 183 for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional \_\_\_\_\_ shares of common stock from us, at the initial 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 of common stock will be ready for delivery on or about \_\_\_\_\_, 2020.

**BofA Securities**

**Morgan Stanley**

**Stifel**

**Wells Fargo Securities**

**Canaccord Genuity**

The date of this prospectus is \_\_\_\_\_, 2020

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We 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 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, 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 of the United States.

## PROSPECTUS SUMMARY

*This summary highlights, and is qualified in its entirety by, the more detailed information and financial statements included 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, including the sections titled “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision.*

*Unless the context otherwise requires, the terms “Pulmonx,” “the company,” “we,” “us,” “our” or similar terms in this prospectus refer to Pulmonx Corporation and its consolidated subsidiaries.*

### Overview

We are a commercial-stage medical technology company that provides a minimally invasive treatment for patients with severe emphysema, a form of chronic obstructive pulmonary disease (COPD). Our solution, which is comprised of the Zephyr Endobronchial Valve (Zephyr Valve), the Chartis Pulmonary Assessment System (Chartis System) and the StratX Lung Analysis Platform (StratX Platform), is designed to treat severe emphysema patients who, despite medical management, are still profoundly symptomatic and either do not want or are ineligible for surgical approaches. We estimate our solution currently addresses approximately 500,000 patients in the United States and 700,000 patients in select international markets, which represents a global market opportunity of approximately \$12 billion.

We have a compelling body of clinical evidence with over 100 scientific articles published regarding the clinical benefits of Zephyr Valves, including in *The New England Journal of Medicine*, *The Lancet* and the *American Journal of Respiratory and Critical Care Medicine*. Multiple randomized controlled clinical trials have demonstrated that patients selected with the Chartis System and successfully treated with Zephyr Valves have shown statistically and clinically significant improvements in lung function, exercise capacity and quality of life compared to medical management alone.

In June 2018, we received pre-market approval (PMA) by the U.S. Food and Drug Administration (FDA) as a result of our breakthrough technology designation. The Zephyr Valve is now commercially available in more than 25 countries, with over 76,000 valves used to treat more than 19,000 patients through December 31, 2019. We have established reimbursement in major markets in North America, Europe and Asia Pacific and the Zephyr Valve has been included in treatment guidelines for COPD worldwide.

### COPD and Emphysema: A Prevalent Disease with High Unmet Medical Needs

COPD refers to a group of lung diseases characterized by obstruction of airflow that interferes with normal breathing. In 2015, it affected approximately 175 million patients and was responsible for 3.2 million deaths globally. In the United States, COPD is the third leading cause of death and affected approximately 16 million Americans as of 2013. COPD is expected to be associated with approximately \$49 billion in direct medical costs in 2020. Emphysema, a form of COPD, which accounts for approximately 25% of all COPD patients, is a debilitating and life-threatening disease that progressively destroys lung tissue, resulting in a diminishing ability to breathe and engage in the most basic daily activities, leading to a high mortality rate. The lung damage caused by emphysema is irreversible. As of 2018, approximately 3.8 million patients in the United States were diagnosed with emphysema, of which roughly 1.5 million have severe emphysema. Of these 1.5 million severe emphysema patients, we estimate that approximately 500,000 patients would qualify for treatment with our Zephyr Valves, and an additional number may be able to be treated in the future with other technologies under development by us if successfully developed and approved.

There are several treatment options for patients with emphysema, depending on the level of severity of the disease, ranging from medical management to more invasive surgical options. However, these treatment options have significant limitations for patients with severe emphysema. Initial treatment for emphysema is generally limited to

medications that primarily target airway obstruction and reduce inflammation, but do not address the underlying lung tissue destruction.

As the disease worsens, symptoms increase despite optimized drug therapy, pulmonary rehabilitation exercises and supplemental oxygen. Many patients become increasingly unable to engage in the most basic daily activities as a result of the persistent feeling of breathlessness and this reduces their overall health status each year. At this point, physicians may refer patients to thoracic surgeons for single or double lung transplantation, or for lung volume reduction surgery (LVRS), in which hyperinflated tissue is cut away and removed. These invasive surgical procedures involve substantial risk of complications, prolonged hospital stays and high mortality. In addition, many patients do not qualify for these procedures. We believe there is both an urgent clinical need and a strong market opportunity for a solution that is safe, effective and minimally invasive.

### **Our Solution**

Our solution, which is comprised of the Zephyr Valve, Chartis System and StratX Platform, is designed to address the need for a more effective, minimally invasive treatment option for patients with severe emphysema, offering bronchoscopic lung volume reduction without surgery and its associated risks. It is used to treat patients who, despite medical management, are still profoundly symptomatic and either do not want or are ineligible for surgical approaches.

Zephyr Valves are indicated for bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. During the one-time bronchoscopic procedure, Zephyr Valves are placed in the airways to occlude the most diseased parts of the lung, allowing trapped air to escape until the lobe is reduced in size. The intended result is a reduction in lung volume and hyperinflation in the targeted lobe, allowing healthier parts of the lung to expand and take in more air. Patients who are successfully treated with the Zephyr Valve report improved breathing and the ability to go back to doing everyday tasks more easily. When combined with the Chartis System for informed patient selection and treatment planning, Zephyr Valves have been shown to have successful procedure rates of 84-90% in clinical trials.

We believe our solution provides the following important benefits:

- **Significant, durable improvements in lung function, exercise capacity and quality of life**, demonstrated in a substantial body of clinical data;
- **Well-characterized safety profile**, evidenced by the inclusion in global treatment recommendations and over 19,000 patients treated globally with the Zephyr Valve;
- **High procedural success** driven by innovative and effective patient assessment tools; and
- **Minimally invasive procedure** typically lasting less than an hour.

Over 100 scientific articles have been published regarding the clinical benefits of Zephyr Valves, including multiple meta-analyses, review articles, cost-effectiveness analyses and risk-benefit analyses. The Zephyr Valve showed statistically significant improvements in lung function, exercise capacity and quality of life when compared to medical management alone in multiple randomized controlled clinical trials. Additionally, independent studies have demonstrated that Zephyr Valves deliver increases in the BODE Index (a multi-dimensional health status scoring system for patients with COPD) that have been associated with survival benefits.

The LIBERATE study, our pivotal study published in 2018, was a multicenter, multinational, randomized controlled clinical trial of Zephyr Valves that included 190 patients with severe emphysema and little to no collateral ventilation. All primary and secondary endpoints were statistically significant, including the proportion of patients achieving a clinically significant improvement in lung function as well as the mean improvements in exercise capacity, hyperinflation and quality of life. These outcomes were the result of a high rate of procedural success, with 84% of patients achieving a clinically meaningful reduction in treated lobe volume.

## Our Success Factors

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

- ***Innovative, minimally invasive treatment paired with proprietary patient selection technology.*** We have developed the first FDA-approved implant, the Zephyr Valve, to reduce hyperinflation associated with severe emphysema, which received a breakthrough technology designation and pre-market approval. To enhance optimal outcomes with the Zephyr Valve, the Chartis System and the StratX Platform are designed to help physicians identify and treat those patients most likely to benefit from treatment with Zephyr Valves. We believe the combination of our innovative valve treatment and patient assessment tools represents a significant competitive advantage and our goal is to establish our solution as a standard of care for severe emphysema.
- ***Addressing a large underserved market.*** We are addressing a large underserved market for patients with severe emphysema whose treatment options are limited. We believe our solution currently addresses approximately 500,000 patients in the United States and 700,000 patients in select international markets who have severe emphysema with hyperinflation and limited to no collateral ventilation, representing an approximately \$12 billion global market opportunity. We have established significant momentum in addressing this market with our broad global commercial footprint across more than 25 countries and with a track record of more than 19,000 patients treated. Additionally, we have ongoing research and development efforts to further expand the addressable market of our products.
- ***Compelling body of clinical evidence and inclusion in COPD guidance documents.*** The safety, effectiveness and clinical advantages of Zephyr Valves have been demonstrated in multiple randomized controlled clinical trials. The quality of evidence for treatment with endobronchial valves has been graded “A” by the Global Initiative for Chronic Obstructive Lung Disease (GOLD), and the United Kingdom’s National Institute for Health and Care Excellence (NICE) has included this treatment as part of standard measures for COPD and recommended all qualifying patients be evaluated for eligibility.
- ***Favorable coverage and established reimbursement.*** In the United States, our solution is reimbursed based on established Category I Current Procedural Terminology (CPT) and ICD-10 Procedure Coding System (PCS) codes and associated MS-DRG and APC payment groupings. Current reimbursement in the United States is generally sufficient to cover the hospital costs of the procedure and related inpatient care. Commercial payors, such as Aetna and Humana, have issued positive coverage policies for the Zephyr Valve, and United Healthcare no longer considers the procedure unproven or experimental. Medicare covers our solution for patients when medically necessary, and other commercial insurers are approving pre-authorization requests on a case-by-case basis. We estimate that roughly 75% of the potential Zephyr Valve patient population are Medicare/Medicaid beneficiaries, of which approximately 25% have managed Medicare/Medicaid and the remaining 50% have traditional Medicare/Medicaid. Approximately 25% of potential Zephyr Valve patient population is under third-party commercial payor policies. Outside the United States, our solution is covered by major health systems across much of Europe, Australia and South Korea.
- ***Comprehensive approach to market development and patient engagement.*** We have established a stepwise approach to market development across three key stakeholders in severe emphysema treatment: hospitals, physicians and patients. Our commercial organization is focused on working with pulmonary physicians and their hospitals to build emphysema centers of excellence where physicians are instructed in the workup of advanced COPD and perform bronchoscopic lung volume reduction using our solution. Our team works closely with all members of the hospital care team to help these centers efficiently incorporate our solution as a new service line. In addition, we are partnering with these centers to build awareness and referrals from primary care and other physicians who may be managing severe emphysema patients in the community. We build upon this approach with direct-to-patient marketing initiatives that help educate patients on the Zephyr Valve procedure and where it is available. We believe

that this comprehensive approach to engagement across multiple constituents will help to increase awareness of and demand for our solution.

- **Robust intellectual property portfolio.** We own intellectual property that covers the Zephyr Valve and Chartis System. As of December 31, 2019, we held 37 U.S. patents and 82 international patents that include device, apparatus and method claims. In addition, we believe that our trade secrets, including manufacturing know-how, provide additional barriers to entry.

## Our Growth Strategy

Our vision is to be a global leader in treating advanced lung disease and to have a transformational impact on the lives of patients. Our goal is to establish our solutions as the standard of care for the assessment and treatment of patients with severe COPD.

Key elements of our strategy to achieve this vision include:

- **Expanding our commercial organization in the United States to drive adoption of Zephyr Valves.** We currently sell Zephyr Valves to more than 80 hospitals and have 32 sales territory managers in the United States. We plan to expand our commercial organization by recruiting and training talented sales territory managers in existing and new markets in the United States to help facilitate further adoption and broaden awareness of Zephyr Valves primarily among the approximately 800 pulmonologists performing interventional pulmonary procedures across approximately 500 high volume hospitals .
- **Collaborating with hospitals to address unmet patient needs.** Our strategy is to identify regions with high unmet need, identify leading hospitals and work with champions of our solution to build emphysema centers of excellence.
- **Promoting awareness among patients, physicians and other healthcare providers.** We intend to continue to promote awareness of our solution through training and educating patients, physicians, pulmonary rehabilitation centers, key opinion leaders and various medical societies on the proven clinical benefits of Zephyr Valves. 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.
- **Continuing to invest in research and development to foster innovation and expand our addressable market.** We intend to continue investing in existing and next generation technologies to address the needs of patients with severe COPD.
- **Expanding in existing and new international markets.** We have established a leading international sales force in interventional pulmonology. We intend to continue expanding our team and seeking additional international regulatory clearances in order to more fully penetrate this global opportunity.
- **Driving profitability by scaling our business operations to achieve cost and production efficiencies.** We plan to drive profitability and gross margin expansion by leveraging our manufacturing capacity to scale production volume, improve efficiencies and lower costs as we increase supply to meet the anticipated growing demands for our products.

We generated revenue of \$      million, with a gross margin of      % and a net loss of \$      million, for the year ended December 31, 2019 compared to revenue of \$20.0 million, with a gross margin of 61.4% and a net loss of \$18.5 million, for the year ended December 31, 2018. As of December 31, 2019, we had an accumulated deficit of \$      million. We currently generate most of our revenue from the sales of Zephyr Valves and delivery catheters. We also generate a smaller amount of our revenue from our Chartis System, which is comprised of sales of the balloon catheters, usage fees and sales of the Chartis console. The StratX Platform, while used to identify patients eligible for treatment with Zephyr Valves, does not independently generate any revenue for us.



## Risk Factors

Our business is subject to numerous risks and uncertainties 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 in the section titled "Risk Factors" immediately following this prospectus summary in deciding whether to invest in our common stock. These risks include, among others, the following:

- We have a history of significant net losses, which we expect to continue, and we may not be able to achieve or sustain profitability in the future;
- We have limited experience marketing and selling our solution;
- We currently rely on a single product, the Zephyr Valve, which can only be marketed for limited indications, and if we are not successful in commercializing the Zephyr Valve, our business, financial condition and results of operations will be negatively affected;
- Our business is dependent on hospital, physician and patient adoption of our solution as a treatment for severe emphysema. If hospitals, physicians or patients are unwilling to change current practices to adopt our solution, it will negatively affect our business, financial condition and results of operations;
- If we fail to receive access to hospital facilities, our sales may decrease;
- Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations;
- If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our solution, or any future products we may seek to commercialize, or if patients are left with significant out-of-pocket costs, our commercial success may be severely hindered;
- If we fail to retain marketing and sales personnel and, as we grow, fail to increase our marketing and sales capabilities or develop broad awareness of our solution in a cost-effective manner, we may not be able to generate revenue growth;
- We have limited long-term data regarding the safety and effectiveness of our solution, including the Zephyr Valve. The only safety and effectiveness data of our solution, including the Zephyr Valve, is limited to one year following placement and we are required to conduct extension studies to follow up on safety and effectiveness out to five years ;
- We have limited experience manufacturing our products in significant commercial quantities and we face manufacturing risks that may adversely affect our ability to manufacture our products, reduce our gross margins and negatively affect our business, financial condition and results of operations;
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide;
- The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate and may decline. Certain patients may not have regions of the lung with little to no collateral ventilation, making them poor candidates for the Zephyr Valve. In addition, if the overall rate of smokers continues to decline, this may eventually decrease the number of patients suffering from COPD and emphysema and, accordingly, who would benefit from our solution;

- We expect to continue to incur net losses for the next several years and we expect to require substantial additional capital beyond the proceeds of this offering to finance our planned operations, which may include future equity and debt financings. This additional capital may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our commercialization, sales and marketing efforts, product development programs or other operations ;
- Our history of recurring losses and anticipated expenditures raise substantial doubts about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations;
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad. If we fail to obtain and maintain necessary regulatory approvals for the Zephyr Valve and related products, or if approvals for future products and indications are delayed or not issued, it will negatively affect our business, financial condition and results of operations; and
- We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

If we are unable to adequately address these and other risks we face, our business may be harmed.

### **Implications of Being an Emerging Growth Company**

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act) and therefore we intend to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these exemptions for up to five years or until we are no longer qualify as an “emerging growth company,” whichever is earlier. In addition, the JOBS Act provides that an “emerging growth company” can delay adopting new or revised accounting standards until those standards apply to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies.

### **Corporate Information**

We were initially incorporated under the laws of the State of California in December 1995 under the name Pulmonx. We reincorporated under the laws of the State of Delaware in December 2013 under the name Pulmonx Corporation.

Our principal executive offices are located at 700 Chesapeake Drive, Redwood City, California 94063. Our telephone number is 1-650-364-0400. Our website address is [www.pulmonx.com](http://www.pulmonx.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 any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

“Pulmonx,” the Pulmonx logo, and other trademarks or service marks of Pulmonx Corporation appearing in this prospectus are the property of Pulmonx Corporation. This prospectus contains additional trade names, trademarks, and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or TM symbols.

## The Offering

Common stock offered by us	shares.
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock at the public offering price less estimated underwriting discounts and commissions.
Use of proceeds	We estimate the net proceeds to us from issuance and sale of shares of our common stock in this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their option to purchase additional shares in full, based upon an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock and facilitate our future access to the capital markets. We currently 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 Asia Pacific to promote the sales of Zephyr Valves, to fund product development and research and development activities, in accordance with the terms of the Loan and Security Agreement (Oxford Agreement) with Oxford Finance LLC (Oxford) and based on the amount drawn thereunder, to pay a success fee of \$1.9 million to Oxford on the completion of this offering and the remaining proceeds for working capital and general corporate purposes, including acquisitions or strategic investments in complementary businesses or technologies, although we do not currently have any plans for any such acquisitions or investments. These expectations are subject to change. See "Use of Proceeds" for additional information.
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 11 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	"PMNX"

The number of shares of our common stock that will be outstanding after this offering is based on 196,835,746 shares of common stock outstanding as of December 31, 2019, which includes 175,832,872 shares of common stock issuable upon the conversion of all of our outstanding shares of convertible preferred stock, and excludes:

- 32,793,421 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2019, at a weighted-average exercise price of \$0.17 per share;
- 2,152,939 shares of our preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2019 with an exercise price of \$1.057 per share, which warrants will expire on the earlier of (i) February 9, 2020 or (ii) the closing of this offering;
- 776,032 shares of our common stock reserved for issuance under our 2010 Stock Plan, which shares will cease to be available for issuance at the time our 2020 Equity Incentive Plan becomes effective;

- shares of our common stock reserved for future issuance pursuant to our 2020 Equity Incentive Plan, which will become effective prior to the completion of this offering and will include provisions that automatically increase the number of shares of common stock reserved for issuance thereunder each year;
- shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective prior to the completion of this offering and will include provisions that automatically increase the number of shares of common stock reserved for issuance thereunder each year; and
- 4,155 shares of our common stock held as treasury stock.

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

- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 175,832,872 shares of our common stock immediately upon the closing of this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation in Delaware and the adoption of our amended and restated bylaws, each of which will occur in connection with the closing of this offering;
- no exercise of outstanding options or warrants after December 31, 2019; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

### Summary Consolidated Financial Data

The following tables summarize, for the periods and as of the dates indicated, our consolidated financial data. We have derived the consolidated statements of operations data for the years ended December 31, 2018 and 2019 and the consolidated balance sheet data as of December 31, 2019 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

When you read this summary consolidated financial data, it is important that you read it together with the historical consolidated financial statements and related notes to those statements, as well as “Selected Consolidated Financial and Other Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included elsewhere in this prospectus.

	Years Ended December 31,	
	2018	2019
(in thousands, except share and per share amounts)		
<b>Consolidated Statement of Operations Data:</b>		
Revenue	\$ 20,004	\$
Cost of goods sold	7,718	
Gross profit	12,286	
Operating expenses:		
Research and development	6,991	
Selling, general and administrative	20,347	
Total operating expenses	27,338	
Loss from operations	(15,052)	
Interest income	21	
Interest expense	(2,520)	
Other income (expense), net	(916)	
Net loss before tax	(18,467)	
Income tax expense	12	
Net loss	(18,479)	
Net loss per share attributable to common stockholders, basic and diluted <sup>(1)</sup>	\$ (1.10)	\$
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted <sup>(1)</sup>	16,748,545	
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) <sup>(1)</sup>		\$
Pro forma weighted-average shares outstanding, basic and diluted (unaudited) <sup>(1)</sup>		

(1) For an explanation of the method used to calculate our historical and pro forma basic and diluted net loss per share and weighted average number of shares used in the computation of per share amounts, see Note 12 to our consolidated financial statements included elsewhere in the prospectus.

As of December 31, 2019

	Actual	Pro forma <sup>(1)</sup>	Pro forma as Adjusted <sup>(2)(3)</sup>
(in thousands)			
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents			
Working capital <sup>(4)</sup>			
Total assets			
Convertible preferred stock warrant liability			
Term loan			
Total liabilities			
Convertible preferred stock			
Accumulated deficit			
Total stockholders' (deficit) equity			

- (1) The pro forma consolidated balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock and shares of our convertible preferred stock to be issued as a result of the assumed exercise of the convertible preferred stock warrants per (iii) below into an aggregate of \_\_\_\_\_ shares of common stock, which will occur upon the closing of this offering; (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur in connection with the closing of this offering; (iii) the assumed exercise of the convertible preferred stock warrants into \_\_\_\_\_ shares of our convertible preferred stock for \$ \_\_\_\_\_ resulting in the issuance of common stock and the related reclassification of the convertible preferred stock warrant liability to common stock and additional paid-in capital immediately upon the closing of this offering and (iv) the payment of a \$1.9 million success fee to Oxford in accordance with the terms of the Oxford Agreement.
- (2) Reflects the pro forma adjustments described in footnote (1) and the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the range set forth on the cover of this prospectus), would increase (decrease) the amount of each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by \$ \_\_\_\_\_ 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 underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase (decrease) the number of shares we are offering. Each increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by \$ \_\_\_\_\_ million, assuming the assumed initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the range set forth on the cover of this prospectus), remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.
- (4) We define working capital as current assets less current liabilities. See our audited consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities as of December 31, 2019.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this prospectus, including our consolidated financial statements and the related notes appearing at the end of this prospectus and the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding to invest in our common stock. Any of these events could cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. Our business, results of operations, financial condition, ability to accomplish our strategic objectives or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material.*

### **Risks Related to Our Business and Strategy**

***We have a history of significant net losses, which we expect to continue, and we may not be able to achieve or sustain profitability in the future.***

We have incurred net losses since our inception. For the year ended December 31, 2019, we had net losses of \$            and we expect to continue to incur additional losses. As of December 31, 2019, we had an accumulated deficit of \$            million. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we grow our sales force and expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, we expect our general and administrative expenses to increase following this offering due to the additional costs associated with being a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time.

***We have limited experience marketing and selling our solution.***

We began commercializing our solution and the Zephyr Valve in the United States in 2018 and, through our predecessors, in Europe in 2003. Our limited commercialization experience and limited number of approved or cleared products make it difficult to evaluate our current business and predict our future prospects. These factors also make it difficult for us to forecast our future financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to successfully complete clinical trials and obtain pre-market approval or 510(k) clearance by the FDA for future planned products in the United States or in key international markets. Our commercialization efforts will depend on the efforts of our management and sales team, our third-party suppliers, physicians and hospitals, and general economic conditions, among other factors, including the following:

- the effectiveness of our marketing and sales efforts in the United States and internationally;
- our success in educating physicians and patients about the benefits, administration and use of the Zephyr Valves;
- the acceptance by physicians, patients and payors of the safety and effectiveness of the Zephyr Valves, including the long-term data;
- our third-party suppliers’ ability to supply the components of the Zephyr Valves in a timely manner, in accordance with our specifications and in compliance with applicable regulatory requirements, and to remain in good standing with regulatory agencies;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing therapies;

- our ability to obtain, maintain and enforce our intellectual property rights in and to the Zephyr Valves;
- the emergence of competing technologies and other adverse market developments, and our need to enhance the Zephyr Valves or develop new products to maintain market share in response to such competing technologies or market developments;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of the Zephyr Valves; and
- our ability to achieve and maintain compliance with all regulatory requirements applicable to the Zephyr Valves.

If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, it will negatively affect our business, financial condition and results of operations.

***We currently rely on a single product, the Zephyr Valve, which can only be marketed for limited indications, and if we are not successful in commercializing the Zephyr Valve, our business, financial condition and results of operations will be negatively affected.***

Our business currently depends entirely on our ability to successfully commercialize the Zephyr Valve, as well as our overall solution, in a timely manner. We have no other therapeutic products currently approved for sale in the United States and we may never be able to develop additional marketable products or enhancements to the Zephyr Valve solution. Currently, our solution is only available to treat patients with severe emphysema in the United States and additional limited indications internationally where we have obtained the necessary regulatory approvals or clearances. Therefore, we are dependent on widespread market adoption of our solution for this limited use-case and we will continue to be dependent on this use-case for the foreseeable future. There can be no assurance that our solution will gain a substantial degree of market acceptance among specialty physicians, patients or healthcare providers. Our failure to successfully increase sales of our solution or develop solutions that address forms of COPD beyond severe emphysema and obtain any necessary regulatory approvals or clearances in connection therewith could negatively affect our business, financial condition and results of operations.

***Our success depends in large part on the success of the Zephyr Valve. If we are unable to successfully market and sell the Zephyr Valves, as well as our overall solution, to patients with severe emphysema, it will negatively affect our business, financial condition and results of operations.***

Our success will depend on our ability to bring awareness to our solution, and the Zephyr Valve in particular, and educate hospitals and physicians regarding the benefits of our solution over existing products and services and to encourage those parties to recommend our solution to their patients. Sales of Zephyr Valves accounted for substantially all of our revenue for the year ended December 31, 2018 and we expect that sales of Zephyr Valves will continue to account for the substantial majority of our revenue going forward. We do not know if our solution will be successful over the long term. Moreover, market acceptance may be hindered if physicians are not presented with compelling data demonstrating the efficacy of our solution compared to alternative procedures and technologies. Any studies we, or third parties which we sponsor, may conduct comparing our solution with alternative treatments for severe emphysema will be expensive, time consuming and may not yield positive results. Additionally, adoption will be directly influenced by a number of financial factors, including the ability of providers to obtain sufficient reimbursement from payors for deploying our solution. The safety, efficacy, performance and cost-effectiveness of our solution, on a stand-alone basis and relative to competing treatments and services, will determine the willingness of payors to cover the procedure. While we have established positive coverage policies with major national private payors, such as Aetna and Humana, other commercial payors, such as the Blue Cross Blue Shield family of plans, do not currently consider our solution medically necessary. No matter the level of coverage by the commercial payor, each patient is generally considered on a case-by-case basis. In addition, Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis. Physicians may be reluctant to recommend our solution to patients covered by such plans with



no specific policies because of the uncertainty surrounding reimbursement, rates and the administrative burden of interfacing with patients to answer their questions and support their efforts to obtain adequate reimbursement for our solution. If physicians do not adopt and recommend our solution, it will negatively affect our business, financial condition and results of operations.

***Our business is dependent on hospital, physician and patient adoption of our solution as a treatment for severe emphysema. If hospitals, physicians or patients are unwilling to change current practices to adopt our solution, it will negatively affect our business, financial condition and results of operations.***

Our primary strategy to grow our revenue is to take a stepwise approach to market development across key stakeholders in severe emphysema treatment, such as hospitals, physicians and patients. To succeed, our sales force must build deep relationships with pulmonary physicians to encourage them and their hospitals to develop emphysema centers of excellence, where physicians are instructed in the workup of advanced COPD and performance of bronchoscopic lung volume reduction using our solution, that offer our solution as a treatment for severe emphysema. In addition, we utilize direct-to-patient marketing initiatives to drive demand through patient empowerment. While the number of hospitals incorporating our solution has increased in recent years, there is a significant group of hospitals and physicians who have not yet adopted our solution, and additional hospitals and physicians may choose not to adopt our solution for a number of reasons, including:

- inadequate recruiting or training of talented sales force in existing and new markets to facilitate outreach and further adoption and awareness of Zephyr Valve;
- lack of experience with our solution and the Zephyr Valve as a treatment alternative;
- the failure of key opinion leaders to continue to provide recommendations regarding the Zephyr Valve, or to assure physicians, patients and healthcare payors of the benefits of the Zephyr Valve as an attractive alternative to other treatment options;
- perceived inadequacy of evidence supporting clinical benefits or cost-effectiveness of our solution over existing alternatives;
- a perception among some physicians of patients' inability to tolerate the procedure required to implant our solution;
- liability risks generally associated with the use of new products and procedures;
- the training required to use new products;
- lack of availability of adequate third-party payor coverage or reimbursement;
- access to hospital bidding processes;
- competing products and alternatives; and
- introduction of other novel alternative therapies to treat severe emphysema.

We focus our sales, marketing and training efforts primarily on pulmonologists. However, physicians from other disciplines, including primary care physicians, as well as other medical professionals, such as nurse practitioners, respiratory technicians, radiologists and community physicians, are often the initial point of contact for patients with severe emphysema.

These physicians and other medical professionals commonly screen and treat patients with severe emphysema, and are likely to recommend medical management, inhaled medications, pulmonary rehabilitation and supplemental oxygen, or more invasive LVRS or lung transplantations. We believe that educating physicians in these disciplines

and other medical professionals about the clinical merits and patient benefits of our solution as a minimally invasive treatment for severe emphysema is a key element of increasing the adoption of our solution. If additional physicians or other medical professionals do not adopt, or existing physician customers cease referring patients to, our solution for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and it will negatively affect our business, financial condition and results of operations.

In addition, patients will not qualify for our solution if, among other potential reasons, their lung anatomy has collateral ventilation that does not allow for effective treatment with the Zephyr Valve, and they may not adopt our solution if they are reluctant to undergo a minimally invasive procedure, they are worried about potential adverse effects of our solution, such as infection, discomfort or weakness, or they are unable to obtain adequate third-party coverage or reimbursement.

***If we fail to receive access to hospital facilities, our sales may decrease.***

In the United States, in order for physicians to use the Zephyr Valve, we expect that the hospital facilities where these physicians treat patients will typically require us to enter into purchasing contracts setting forth the terms and conditions under which the hospital facilities will purchase Zephyr Valves . This process can be lengthy and time-consuming and require extensive negotiations and management time , and potentially result in delays and increases to the sales cycle before we can sell the Zephyr Valve to these hospitals . In the European Union, certain institutions may require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may decrease, and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

***Use of our solution requires appropriate physician training, and inadequate training may lead to negative patient outcomes and negatively affect our business, financial condition and results of operations.***

The successful implantation of the Zephyr Valve depends in part on the training and skill of the physician performing the procedure and on adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train physicians to ensure correct patient selection and treatment planning using the StratX Platform and Chartis System, and proper placement of the Zephyr Valve. Physicians could experience difficulty with the technique necessary to successfully implant the valve and may not achieve the technical competency necessary to complete the training program, or they could fail to properly learn how to interpret our StratX Platform or Chartis System. Moreover, physicians rely on their previous medical training and experience when using our solution, and we cannot guarantee that all such physicians will have the necessary skills to properly identify ideal candidates and to perform the procedure. We do not control which physicians use our solution or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to use our solution. If physicians implant the Zephyr Valve incorrectly, or do so in a manner that is inconsistent with its labeled indications, with components that are not our products, in patients who are not good candidates, or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved in our clinical trials. This result may negatively impact the perception of patient benefit and safety, and limit adoption of our solution as a treatment for severe emphysema and our products that facilitate the procedure, which will negatively affect our business, financial condition and results of operations.

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 commercial organization to train physicians is less than expected or if we are unable to sufficiently grow our sales force. All these events would lead to fewer trained physicians qualified to implant the Zephyr Valve, which could negatively affect our business, financial condition and results of operations.

***Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations.***

The most common serious complications relating to the use of the Zephyr Valve include pneumothoraces, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea, respiratory failure and, in rare cases, death. Pneumothoraces occur when a lung collapses due to an air leak inside the lung and may result from rapid shifts in air volume in the chest as the target lobe deflates and the neighboring lobe expands following the Zephyr Valve treatment. A pneumothorax typically requires placement of a chest tube to manage the air leak. While most pneumothoraces can be readily managed with standard medical care, in rare cases they can be life-threatening, particularly if left untreated. In the event the pneumothorax does not resolve with standard management, one or more valves can be removed to re-inflate the lung; these are typically replaced later when the pneumothorax has resolved.

In our clinical trials, pneumothoraces occurred in 18-34% of patients treated with the Zephyr Valve, and in the LIBERATE study, 17% of the pneumothorax events required no intervention and resolved on their own. Patients who have had their pneumothoraces successfully treated had comparable outcomes to those who did not experience a pneumothorax, other than that their hospital stays were extended by approximately a week compared to the three nights for patients without pneumothoraces.

In the LIBERATE study, the majority of pneumothoraces (76%) occurred within three days following a bronchoscopy procedure. During the Treatment Period (day of procedure to 45 days), there were a total of four deaths (3.1%) in the Zephyr Valve Group (which received Zephyr Valves plus medical management) and none in the Control Group. Three of the four deaths were deemed by the investigators to be definitely related to treatment with Zephyr Valves and the remaining one was deemed by the investigators to be probably related to treatment with Zephyr Valves. Each patient that died experienced pneumothorax, with three deaths directly attributed to the pneumothorax and the fourth death the result of respiratory failure, after the pneumothorax had resolved. Two of the pneumothorax-related deaths occurred early in the study when patients were being kept in the hospital for one night after the procedure. In order to more closely monitor patients, the study protocol was subsequently amended to keep patients in the hospital for five nights. Based on the full study data, current practice is to keep patients in the hospital for a minimum of three nights post-treatment. Post-hoc analysis has helped to identify risk factors for the group of patients at a higher risk of having a complex pneumothorax event (complex pneumothorax defined as requiring removal of all valves or resulting in death) should one occur. Such high-risk patients include those who are not treated in the most diseased lobe and have greater than 60% destruction of the untreated lung. All four patients who experienced a pneumothorax and died were within this high-risk group. This learning is incorporated in our physician training program for physicians to identify such high-risk patients and to consider alternative targets or other risk mitigation strategies. During the Longer-Term Period (46 days after procedure to 12 months), there was one death (0.8%) in the Zephyr Valve Group from a COPD exacerbation, deemed by the investigators not to be related to treatment with Zephyr Valves, and one cardiac arrhythmia related death in the Control Group (1.6%).

Outside of clinical trials, patients treated with the Zephyr Valve have also experienced serious complications, including pneumothoraces and death related to the Zephyr Valve.

Serious complications as a result of treatment with Zephyr Valves, and any increase in the rate of complications in or outside of clinical trials, could cause doctors, hospitals and patients to limit adoption of our solution and subject us to costly litigation, require us to pay substantial amounts of money to patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts, which may negatively impact adoption as well as our business, financial condition and results of operations. Even in a circumstance in which we do not believe that a complication is related to the Zephyr Valve or treatment with the Zephyr Valve, the investigation into the circumstance may be time-consuming or inconclusive and may interrupt our sales efforts or impact and limit the type of regulatory approvals the Zephyr Valve receives or maintains and any related claims may negatively impact adoption as well as our business, financial condition and results of operations. Moreover, perceptions regarding the safety of the Zephyr Valve could be affected even if such complications are unrelated to the Zephyr Valve or treatment with the Zephyr Valve.

Further, our current products are contraindicated, and therefore should not be used, in certain patients, including those for whom bronchoscopic procedures are contraindicated, with evidence of active pulmonary infection, with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium) or silicone, who have not quit smoking, or with large bullae encompassing greater than 30% of either lung, and such contraindication may limit adoption and, as a result, negatively impact our business, financial condition and results of operations.

***If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our solution, or any future products we may seek to commercialize, or if patients are left with significant out-of-pocket costs, our commercial success may be severely hindered.***

We currently derive primarily all of our revenue from sales of the Zephyr Valve solution and expect this to continue for the foreseeable future. We primarily sell Zephyr Valves through a direct sales force that primarily engages with pulmonologists in the United States, Europe and Asia Pacific. Hospitals typically bill various third-party payors to cover all or a portion of the costs and fees associated with the procedures in which our solution is used and bill patients for any deductibles or co-payments. As of December 31, 2019, commercial payors such as Aetna, Humana, Priority Health and Emblem Health have issued positive coverage policies for endobronchial valve procedures. United Healthcare removed the endobronchial valve codes from their non-covered list, and as such no longer considers the procedure unproven or experimental. Other commercial payors, such as many plans in the Blue Cross Blue Shield family of plans, do not yet consider our solution medically necessary. Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis, and other commercial insurers not described above are approving pre-authorization requests on a case-by-case basis.

The Centers for Medicare & Medicaid Services (CMS) have established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a healthcare procedure furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. Any changes in federal legislation, regulations and policy affecting CMS coverage and reimbursement relative to the procedure using our products could have a material effect on our performance. While no national coverage determination (NCD) or local coverage determination (LCD) exists for endobronchial valves currently, CMS could develop an NCD, or one or more Medicare contractors could develop an LCD that either restricts coverage or restricts the patient population deemed appropriate for the treatment.

Physicians that insert the Zephyr Valve, or the hospitals for which they work, may be subject to reimbursement claim denials upon submission of the claim. Physicians or hospitals 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. Whenever possible, pre-authorization for coverage for the procedure is recommended before the procedure is performed. When pre-authorization is not obtained or not allowed, and the procedure is performed and not covered by third-party payors, physicians or hospitals typically directly bill patients enrolled with these third-party payors for the costs and fees associated with the procedures in which our products are used. Moreover, because there is often no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our solution can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target physicians and hospitals 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 physicians and hospitals could make it difficult for existing physicians and hospitals to continue using or to adopt our solution and could create additional pricing pressure for us. If we are forced to lower the price we charge for our solution, our gross margins will decrease, which will negatively affect our business, financial condition and results of operations.

Outside of the United States, reimbursement levels vary significantly by country and by patient. Reimbursement is obtained from a variety of sources, including government sponsors, hospital budgets, or private health insurance plans, or combinations thereof. We have established reimbursement access in countries across Europe and Asia Pacific, including Australia, Germany, the Netherlands, South Korea, the United Kingdom and other countries. Even

if we succeed in bringing our products to market in additional foreign countries, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices.

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 solution 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, 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 will negatively affect our business, financial condition and results of operations.

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 solution 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 will negatively affect our business, financial condition and results of operations.

***Third-party payors and physicians who do not cover or use the Zephyr Valve may require additional clinical data prior to maintaining coverage of or adopting the Zephyr Valve.***

Our success depends on physician and third-party payor acceptance of our solution as an effective treatment option for patients with severe emphysema. 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 solution.

In addition, the long-term effects of use of the Zephyr Valve to treat severe emphysema are not yet known. Certain physicians, hospitals and payors may prefer to see longer-term safety and efficacy data published than we have produced. Further, 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.

***If we fail to retain marketing and sales personnel and, as we grow, fail to increase our marketing and sales capabilities or develop broad awareness of our solution in a cost-effective manner, we may not be able to generate revenue growth.***

We have limited experience marketing and selling our solution. We currently rely on our direct sales force to sell our solution in targeted geographic regions and distributors in certain regions outside the United States, and any failure to maintain and grow our direct sales force will negatively affect our business, financial condition and results of operations. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in increasing adoption of our solution. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations.

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase the number of customers and emphysema centers of excellence. Identifying and recruiting qualified sales and marketing personnel and training them on our solution, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may

subject us to higher fixed costs than those of companies with competing techniques or products that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our solution. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our solution will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our solution in a cost-effective manner is critical to achieving broad acceptance of our solution and expanding domestically and internationally. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our solution.

***We have limited long-term data regarding the safety and effectiveness of our solution, including the Zephyr Valve. The only safety and effectiveness data of our solution, including the Zephyr Valve, is limited to one year following placement and we are required to conduct extension studies to follow up on safety and effectiveness out to five years.***

Although we have demonstrated the safety, effectiveness and clinical advantages of our solution in multiple clinical trials in approximately 450 patients selected using the Chartis System, the Zephyr Valve is still a relatively new treatment for severe emphysema. The long-term effects of using our solution in a large number of patients have not been studied and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. We are required to conduct the LIBERATE extension study to follow up on safety and effectiveness out to five years. After the completion of the one-year follow up, 115 Zephyr Valve patients and 47 crossover patients (162 total patients) entered the LIBERATE extension study. The results of this extension study will not be available until February 2023. Our ability to interpret the data from this long-term follow-up of patients with this progressive disease may be limited by the fact that the matched control group exited the study after one year. The results of clinical trials of our solution conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, pre-clinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in pre-clinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

***The continuing development of our products depends upon our maintaining strong working relationships with physicians.***

The research, development, marketing and sale of our current products and potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us in clinical trials and in marketing, and as researchers, product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could negatively affect our business, financial condition and results of operations. At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General (OIG), the U.S. Department of

Justice (DOJ), the state attorneys general and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorneys general and other government agencies, could negatively affect our business, financial condition and results of operations. Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below under "Risks Related to Government Regulation and Our Industry."

***We rely on third parties to perform certain aspects of the CT scan analysis within the StratX Platform.***

We rely on third-party service providers to upload and analyze CT scan data on the StratX Platform. In order to make the StratX Platform available to physicians, we contract with a third-party cloud service. This third-party cloud service enables physicians to upload CT scan data while removing protected health information (PHI) of patients from that data, in case the physicians have, inadvertently, not removed the PHI themselves. We also contract with additional third-party service providers to analyze the CT scan data using their proprietary software, and provide quantitative results via an easy-to-read report that we designed for our solution (StratX Lung Report). The StratX Lung Report is then made available to physicians in the third-party cloud service.

This service is critical and there are relatively few alternative sources of supply. These third-party service providers may be unwilling or unable to provide the necessary services reliably and at the levels we anticipate or that are required by the market. While these third-party service providers have generally met our demand for their 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 services, either because of acts of nature, the nature of our agreements or potential disputes with those service providers or our relative importance to them as a customer, and our service providers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change service providers for any reason, including due to any change in or termination of our relationships with these third parties, we may lose sales, experience 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.

***We depend on a limited number of single-source suppliers to manufacture our products, which makes us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.***

We rely on single-source suppliers for the components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and there are no or relatively few alternative sources of supply. These single-source suppliers 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. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for 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 suppliers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change suppliers due to any change in or termination of our relationships with these third parties, or if our suppliers 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.

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

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the FDA's Quality System Regulation (QSR) and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

***We have limited experience manufacturing our products in significant commercial quantities and we face manufacturing risks that may adversely affect our ability to manufacture our products, reduce our gross margins and negatively affect our business, financial condition and results of operations.***

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a facility located in Redwood City, California, where we assemble, inspect, package, release and ship our products. We currently produce the Zephyr Valve and Chartis System at this facility, and we do not have redundant facilities. If this facility suffers damage, or a force majeure event, this could materially impact our ability to operate.

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

- quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, that are required to meet our quality specifications, many of whom are our single source suppliers for the products they supply;
- our inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- our failure to increase production capacity or volumes to meet demand;
- our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

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



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

To ensure adequate inventory supply, we must forecast inventory needs and manufacture the Zephyr Valve and Chartis System based on our estimates of future demand for our solution. Our ability to accurately forecast demand for our solution 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 solution 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 solution, our internal manufacturing team 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 may not be able to allocate sufficient capacity in order to meet our increased requirements, which will negatively affect our business, financial condition and 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.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.***

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our products and any approved products, which may vary significantly;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the timing and cost of obtaining regulatory approvals or clearances for planned or future products or indications;
- unanticipated pricing pressures;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- our ability to expand the geographic reach of our sales force;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to our products, and potential future products that compete with our products;

- the timing and success or failure of pre-clinical studies or clinical trials for our products or any future products we develop or competing products;
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry;
- the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold, including any related foreign currency impact;
- seasonality, including possible seasonal slowing of demand for our products in the fourth quarter and summer months based on the elective nature of procedures performed using our products, and which may become more pronounced in the future as our business grows;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- the average number of Zephyr Valves used for a patient, pricing, discounts and incentives; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance.

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

***The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate and may decline. Certain patients may not have regions of the lung with little to no collateral ventilation, making them poor candidates for the Zephyr Valve. In addition, if the overall rate of smokers continues to decline, this may eventually decrease the number of patients suffering from COPD and emphysema and, accordingly, who would benefit from our solution.***

Our estimates of the annual total addressable markets for our current solution and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients with severe emphysema treatable by our solution and the assumed prices at which we can sell our solution in markets that have not yet been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors.

For example, certain of these patients may not have regions of the lung with little to no collateral ventilation, making them poor candidates for the Zephyr Valve. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect.

Further, cigarette smoking is one of the leading causes of COPD and emphysema. It is estimated that smoking accounts for as many as 80% of COPD-related deaths and 38% of nearly 16 million adults in the United States diagnosed with COPD report being current smokers. The overall rate of smoking among the U.S. adult population has been steadily declining from 42.4% in 1965 to a record low of 13.7% in 2018 and there are increased efforts to decrease the rate of smoking globally. If the overall rate of smokers continues to decline, this may eventually decrease the number of patients suffering from COPD and emphysema and, accordingly, who would benefit from our solution.

If the actual number of patients who would benefit from our solution, the price at which we can sell future products, or the annual total addressable market for our solution is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

***Failure of a key information technology system, process, or site could negatively affect our business, financial condition and results of operations.***

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management. We also depend on the information technology systems of third parties for the analysis, data storage and communication associated with the StratX Platform. We currently do not have redundant information technology systems. Our information technology systems, and those of third parties, may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We, or the third parties we rely upon, could be subject to an unintentional event that involves a third party gaining unauthorized access to our or its systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions would disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability use our products for treatments. Moreover, a disruption in access to the system that controls the StratX Platform would prevent physicians using our solution from receiving the StratX Lung Report indicating whether their patients are good candidates for the Zephyr Valve. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and negatively affect our business, financial condition and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. Further, we do not carry any cyber insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could negatively affect our business, financial condition and results of operations.

***Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.***

We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by our customers in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients or vendors of our customers, or stockholders. For example, our Swiss subsidiary is currently party to a lawsuit with a former distributor outside the United States alleging that our Swiss subsidiary conducted unfair competitive practices and violated the exclusive distribution rights as a result of its termination of its distribution agreement. While we believe the claims are meritless and do not believe the impact of such claims will be material to the Company's results of operations or financial position, an unfavorable outcome in this litigation could harm our business. Further, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, and this risk is especially relevant to industries that experience significant stock price volatility. Any litigation involving us may result in substantial

costs, operationally restrict our business, and may divert management’s attention and resources, which may negatively affect our business, financial condition and results of operations.

***We face the risk of product liability claims that would 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. The Zephyr Valve 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 the Zephyr Valve 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. As discussed under “Business—Clinical Trials and Results,” there were procedure-related deaths in our LIBERATE Study and we may be subject to product liability claims if the Zephyr Valve 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, physicians, or others selling or otherwise coming into contact with the Zephyr Valve, 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 solution or new products;
- decreased demand for our products;
- 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 solution, either of which could negatively affect our business, financial condition and results of operations.

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

We do not carry insurance for all categories of risk that our business may encounter. Although we have 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 negatively affect our business, financial condition and results of operations. We do not carry specific hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Additionally, we do not carry cyber insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources.

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

***Our indebtedness may limit our flexibility in operating our business and negatively affect our business, financial condition, results of operations and competitive position.***

As of December 31, 2019, we had \$ \_\_\_\_\_ of indebtedness outstanding under the Oxford Agreement.

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 Oxford Agreement 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 the Oxford 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 negatively affect our business, financial condition and results of operations.

***Our industry is highly competitive, and we may not be able to compete successfully with larger companies, companies with longer operating histories or more established products, or companies with greater resources.***

Our industry is subject to rapid change from the introduction of new products and technologies and other activities of industry participants. Our goal is to establish our solution as a standard of care for severe emphysema. Existing treatments include medical management, LVRS, lung transplantation as well as other minimally invasive treatments. The major competitive products include the Spiration Valve System (Olympus Corporation) and the InterVapor System (Broncus Medical, Inc.; not approved for use in the United States). The Spiration Valve System is an endobronchial technology designed to offer patients with severe emphysema a minimally invasive treatment option for lung volume reduction by redirecting air away from diseased areas of the lung to healthier tissue so that patients may breathe easier. Like Zephyr Valves, the Spiration Valve System is indicated to treat patients with heterogeneous emphysema; however, the Spiration Valve System is contraindicated for patients with homogeneous emphysema. The InterVapor System offers a non-surgical and non-implant therapy developed for lung disease including emphysema and lung cancer where vapor ablation is simply the application of heated pure water to tissue. These technologies, other products that are in current clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and patient acceptance.

We compete, or may compete in the future, against other companies which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results. These companies enjoy several competitive advantages, including established relationships with pulmonologists who commonly treat patients with emphysema, significantly greater name recognition and significantly greater sales and marketing resources.

In addition to existing competitors, other larger and more established companies may acquire or in-license competitive products and could directly compete with us. These competitors may also try to compete with us on price both directly, through rebates and promotional programs to high volume physicians and coupons to patients, and indirectly, through attractive product bundling with complementary products that offer convenience and an effectively lower price compared to the total price of purchasing each product separately. Larger competitors may also be able to offer greater customer loyalty benefits to encourage repeat use of their products and finance a sustained global advertising campaign to compete with commercialization efforts of our products. Our competitors may seek to discredit our products by challenging our short operating history or relatively limited number of scientific studies and publications. Smaller companies could also launch new or enhanced products and services that we do not offer and that could gain market acceptance quickly. Additionally, certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. As more companies develop new intellectual property in our market, there is the possibility of a competitor acquiring patents or other rights that may limit our ability to update our technologies and products which may impact demand for our products.

***We have increased the size of our organization and expect to further increase it in the future. If we are unable to manage the anticipated growth, our business, financial condition and results of operations will be negatively affected.***

Any growth that we experience in the future will require us to expand our sales personnel and manufacturing operations and general and administrative infrastructure. As a public company, we will need to support managerial, operational, financial and other resources. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our solution, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and negatively affect our business, financial condition and results of operations.

As demand for our solution or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing data or inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation will be harmed and negatively affect our business, financial condition and results of operations.

***We expect to continue to incur net losses for the next several years and we expect to require substantial additional capital beyond the proceeds of this offering to finance our planned operations, which may include future equity and debt financings. This additional capital may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our commercialization, sales and marketing efforts, product development programs or other operations .***

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. Since our inception, our operations have been financed primarily through private placements of equity securities, debt financing arrangements and sales of our products. As of December 31, 2019, we had \$ million in cash and cash equivalents, and an accumulated deficit of \$ million. Based on our current planned operations, we expect our cash and cash equivalents, together with available borrowings under the Oxford Agreement and the proceeds from this offering, will enable us to fund our operating expenses for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We expect to continue to make substantial investments in clinical trials that are designed to provide clinical evidence of the safety and efficacy of our solution. We intend to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales territory managers and expanding our international sales and marketing programs to help promote awareness and increase adoption of our solution primarily among the approximately 800 pulmonologists performing interventional pulmonary procedures across approximately 500 high volume hospitals. In order to continue to grow our business, we will need to hire additional sales personnel to efficiently serve the market. We also expect to continue to make investments in research and development, regulatory affairs and clinical studies to develop future generations of our solution, broaden the addressable market and expand indications, support regulatory submissions and demonstrate the clinical efficacy of our solution. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and Securities and Exchange Commission (SEC) compliance, investor relations and other expenses. Because of these and other factors, we expect to continue to incur substantial net losses

and negative cash flows from operations for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales from our current solution and potential future products;
- the degree of success we experience in continuing to commercialize our solution;
- the emergence of competing or complementary technologies;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We will require additional financing to fund working capital and pay our obligations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings or debt financings. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating expenses, which may negatively affect our business, financial condition and results of operations. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional capital may not be available on reasonable terms, or at all.

***If the quality of our solution does not meet the expectations of physicians or patients, then our business and reputation may be harmed.***

In the course of conducting our business, we must adequately address quality issues that may arise with our solution, including defects in third-party components included in our solution. 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 the Zephyr Valves does not live up to the expectations of physicians or patients as a result of the physician's implantation of the valve. For example, a physician may improperly implant the Zephyr Valve. If the quality of our solution does not meet the expectations of physicians or patients, then our business and reputation with those physicians or patients may negatively affect our business, financial condition and results of operations.

***If our facilities become damaged or inoperable, we will be unable to continue to research, develop and supply our solution which could negatively affect our business, financial condition and results of operations 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 manufacturing, research and development and back office activity and maintain all our finished goods inventory in a single location in Redwood City, California. Our facility, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The facility will be harmed or rendered inoperable by natural or man-made disasters, including,



but not limited to, earthquakes, 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 manufacturing capabilities, 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.

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

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 the Zephyr Valve and Chartis 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 solution 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 the Zephyr Valve on a timely basis.

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

Our success depends 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 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 negatively affect our business, financial condition and results of operations. In addition, we do not carry any key person insurance policies that could offset potential loss of service under applicable circumstances.

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

In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the 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, particularly after the expiration of the lock-up agreements described herein. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

***We have significant international operations, and to successfully market and sell our products in such international markets we must address international business risks with which we have limited experience.***

Sales in markets outside of the United States accounted for approximately % of our revenue for the year ended December 31, 2019. We currently focus our international sales and marketing efforts in Australia, Austria, China, France, Germany, Italy, the Netherlands, South Korea, Spain, Switzerland and the United Kingdom. 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;
- differing payment and reimbursement regimes;
- 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, it will negatively affect our business, financial condition and results of operations.

***Our history of recurring losses and anticipated expenditures raise substantial doubts about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.***

We have incurred operating losses to date and it is possible we will never generate profit. We have concluded that substantial doubt exists regarding our ability to continue as a going concern. Our audited financial statements appearing at the end of this prospectus have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of these uncertainties related to our ability to operate on a going concern basis.

The report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2018 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties due to concerns about our ability to meet our contractual obligations.

***Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or the physicians who use our solution and the patients they treat, or prevent us from assessing critical information and expose us to liability, which could negatively affect our business, financial condition and results of operations and our reputation.***

In the ordinary course of our business, we may become exposed to, or collect and store sensitive data, including procedure-based information and legally PHI, credit card, and other financial information, insurance information, and other potentially personally identifiable information. For example, we may fail to remove all PHI from CT scan data on the StratX Platform. We also store sensitive intellectual property and other proprietary business information. Although we are in the process of implementing policies and procedures designed to ensure compliance with applicable data security and privacy-related laws and regulations and we take measures to protect sensitive information from unauthorized access or disclosure, our information technology (IT) and infrastructure, and other technology partners and providers, may be vulnerable to cyber-attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided or used by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The use of cloud-based computing creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers and we do not carry cyber insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources. Although the aggregate impact on our operations and financial condition has not been material to date, we have occasionally been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. We cannot assure you, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems, and such breakdowns and breaches could negatively affect our business, financial condition and results of operations and our reputation.

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

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop new products or product improvements and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or

arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or viable product improvements or result in significant revenues and could be terminated prior to developing any products.

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

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

***Unfavorable global economic conditions could negatively 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. A severe or prolonged economic downturn, such as the global financial crisis of 2008, could result in a variety of risks to our business, including weakened demand for our solution, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing will negatively affect our business, financial condition and results of operations and we cannot anticipate all of the ways in which the economic climate and financial market conditions could negatively affect our business, financial condition and results of operations.

***We may acquire other companies or technologies, which could divert our management's attention, result in additional dilution to our stockholders and otherwise negatively affect our business, financial condition and results of operations.***

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our current business, enhance our technical capabilities or otherwise offer growth opportunities. 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, applications or technologies instead of developing them ourselves. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or

be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

We may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which will harm our operating results. In addition, if an acquired business fails to meet our expectations, it will negatively affect our business, financial condition and results of operations.

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

The commercial payor industry is undergoing significant consolidation. When payors combine their operations, the combined company may elect to reimburse our products at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payors participating in the consolidation does not reimburse for the Zephyr Valve and our solution at all, the combined company may elect not to reimburse for the same, which would adversely impact our operating results.

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

It is important to our business that we continue to enhance the Zephyr Valve, Chartis System and StratX Platform 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 solution will depend on several factors, including our ability to:

- assemble sufficient resources to acquire or discover additional products;
- properly identify and anticipate physician and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from pre-clinical 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;
- produce new products in commercial quantities at an acceptable cost;
- 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.

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

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

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

***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 negatively affect our business, financial condition and results of operations.***

As we grow our international presence and global operations, we will be increasingly exposed to 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 (FCPA), and other federal statutes and regulations, including those established by the Office of Foreign Assets Control (OFAC). In addition, the U.K. Bribery Act of 2010 (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 are in the process of enhancing 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 negatively affect our business, financial condition and results of operations.

***Our results may be impacted by changes in foreign currency exchange rates.***

A significant proportion of our sales are outside of the United States, and a majority of those are denominated in foreign currencies, which exposes us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful, and our business could be harmed.

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

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code) a corporation that undergoes an ownership change, generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and its research and development credit carryforwards to offset future taxable income. 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.

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

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our solution or maintain prices at the levels we have historically achieved. Any decline in the amount that payers reimburse our customers for the Zephyr Valve and related products could make it difficult for customers to continue using, or to adopt, our solution and could create additional pricing pressure for us. If we are forced to lower the price we charge for our solution, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which will negatively affect our business, financial condition and results of operations.

***Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.***

Our products may be subject to U.S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, will harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic

sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely negatively affect our business, financial condition and results of operations.

### **Risks Related to Government Regulation and Our Industry**

***Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad. If we fail to obtain and maintain necessary regulatory approvals for the Zephyr Valve and related products, or if approvals for future products and indications are delayed or not issued, it will negatively affect our business, financial condition and results of operations.***

The Zephyr Valve is subject to extensive regulation by the FDA in the United States and by our Notified Body in the European Union. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, manufacture, and release;
- laboratory, pre-clinical and clinical testing, labeling, packaging, storage and distribution;
- product safety and efficacy;
- premarketing clearance or approval;
- service operations;
- record keeping;
- product marketing, promotion and advertising, sales and distribution;
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals;
- post-market approval studies; and
- product import and export.

Before a new medical device or service, or a new intended use for an existing product or service, can be marketed in the United States, a company must first submit and receive either 510(k) clearance 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 the Zephyr Valve, 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.



Either the 510(k) or PMA process can be expensive, lengthy and unpredictable. We may not be able to obtain any necessary clearances or approval or may be unduly delayed in doing so, which will negatively affect our business, financial condition and results of operations. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained PMA approval to market the Zephyr Valve, our approval can be revoked if safety or efficacy problems develop.

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 order to sell our products in member countries of the European Economic Area (EEA), our products must comply with the essential requirements of the European Union Medical Devices Directive (Council Directive 93/42/EEC) (MDD) 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 (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 European Commission Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the MDD, a conformity assessment procedure requires the intervention by 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. 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.

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

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for regulatory clearance or premarket approval of new products or services, new intended uses or modifications to existing products or services;
- withdrawal of regulatory clearance or premarket approvals that have already been granted; or
- criminal prosecution.

If any of these events were to occur, it will negatively affect our business, financial condition and results of operations.

***Changes in the regulatory environment may constrain or require us to restructure our operations, which may harm our revenue and operating results.***

Healthcare laws and regulations change frequently and may change significantly in the future. We may not be able to adapt our operations to address every new regulation, and new regulations may negatively affect our business, financial condition and results of operations. We cannot assure you that a review of our business by courts or regulatory authorities would not result in a determination that adversely affects our revenue and operating results, or that the healthcare regulatory environment will not change in a way that restricts our operations. In addition, there is risk that the U.S. Congress may implement changes in laws and regulations governing healthcare service providers, including measures to control costs, or reductions in reimbursement levels, which may negatively affect our business, financial condition and results of operations.

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. CMS, as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U.S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Further reductions of reimbursement by CMS for services or changes in policy regarding coverage of tests or other services provided or other requirements for payment, such as prior authorization or a physician's or qualified practitioner's signature on test/service requisitions, may be implemented from time to time. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians. Reductions in the reimbursement rates and changes in payment policies of other third-party payors may occur as well. Similar changes in the past have resulted in reduced payments as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third-party payor regulations or policies may negatively affect our business, financial condition and results of operations. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also negatively affect our business, financial condition and results of operations.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the MDD 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 become applicable 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 European Union; and
- strengthen 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.

***A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.***

The FDA and similar foreign governmental authorities 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 an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. A future recall announcement will harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device reporting regulations (MDRs), we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDRs. 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 or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances 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. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which will negatively affect our business, financial condition and results of operations, including our ability to market our products in the future.

Any adverse event involving our products, whether in the United States or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. 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.

***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 and negatively affect our business, financial condition and results of operations.***

The products and services we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and clinics may expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products and services. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to our solution and regulatory agencies enforcing those laws and regulations;
- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;
- the federal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Physician Payments Sunshine Act (Open Payments), created under the Patient Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act) and its implementing regulations, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to licensed physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the Federal Drug & Cosmetic Act (FDCA), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the federal physician self-referral prohibition, commonly known as the Stark Law;
- state 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, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation (GDPR), which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union (including health data).

The Affordable Care Act was enacted in 2010. The Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes, including those created under HIPAA. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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 negatively affect our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

Although we have adopted policies and procedures designed to comply with these laws and regulations and conduct internal reviews of our compliance with these laws, our activities, including those relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products (such as our patient reimbursement support program) and the sale and marketing of our products, may be subject to scrutiny by under these laws. Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our activities could be subject to challenge under one or more such laws. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment, for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm and disgorgement and we could be required to curtail or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

***If we modify the Zephyr Valve, we may need to seek additional clearances or approvals, which, if not granted, would prevent us from selling our modified products.***

In the United States, the Zephyr Valve is marketed pursuant to a PMA order issued by the FDA. Any modifications to a PMA-approved device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design,

components, or technology requires approval of a new PMA application or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement - Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new approvals are necessary. If the FDA disagrees with our determination and requires us to seek new PMA approvals for modifications to our previously approved products for which we have concluded that new approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

***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 Zephyr Valve, 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 the Zephyr Valve was subject to several conditions of approval, including extended follow-up of the pre-market study cohort and post market study. Though we believe we have complied with these conditions to date, any failure to comply with the conditions of approval could result in the withdrawal of PMA approval and the inability to continue to market the device. Failure to conduct the required studies in accordance with Institutional Review Board (IRB) and informed consent requirements, or adverse findings in these studies, could also be grounds for withdrawal of approval of the PMA.

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

***If treatment guidelines for severe emphysema 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 severe emphysema 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 will negatively affect our business, financial condition and results of operations.

***If we or our suppliers fail to comply with the FDA's QSR or the European Union Medical Devices Directive, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.***

Our manufacturing and design processes and those of our third-party suppliers are required to comply with the FDA's QSR and the European Union Medical Devices Directive (Council Directive 93/42/EEC) (MDD), both of which cover procedures and documentation of the design, testing, production, control, quality assurance, labeling,

packaging, storage and shipping of Zephyr Valves. We are also subject to similar state requirements and licenses, and to ongoing International Organization for Standardization (ISO) compliance in all operations, including design, manufacturing, and service, to maintain our CE Mark. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, European Union Notified Bodies and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would negatively affect our business, financial condition and results of operations. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenue to decline.

We are registered with the FDA as a manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health (CDPH) to determine our compliance with the QSR and other regulations at our manufacturing facility, and these inspections may include the manufacturing facilities of our suppliers. Our design facilities in Redwood City, California were most recently audited by the FDA in November 2016 and no observations resulting in a warning letter were identified. We believe that we are in compliance, in all material respects, with the QSR.

We also maintain a certificate of registration for the design, manufacture, service, and distribution of our product from British Standards Institution (BSI) in the Netherlands, our European Notified Body. Most recently, the BSI completed an ISO 13485 surveillance audit of our design, manufacturing and service operations in May 2019 and we believe that we are in compliance, in all material respects, with the MDD.

We can provide no assurance that we will continue to remain in compliance with the QSR or MDD. If the FDA, CDPH or BSI inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility, we may be unable to produce our solutions, which will negatively affect our business, financial condition and results of operations.

***The misuse or off-label use of our solution will harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations and sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which will negatively affect our business, financial condition and results of operations.***

Our solution has been approved by the FDA for specific indications. We train our marketing and direct sales force to not promote our products for uses outside of the FDA-approved indications for use, known as “off-label” uses. We cannot, however, prevent a physician from using our products 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 products off-label. Furthermore, the use of our products for indications other than those approved by the FDA or any foreign regulatory body may not effectively treat such conditions, which will harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. 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. In addition, 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 of an untitled letter, 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 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. Any of these events will negatively affect our business, financial condition and results of operations and cause our stock price to decline.

***We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of our products.***

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as “off-label” use. Physicians may use our products off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes 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 of warning letters, untitled letters, fines, penalties, injunctions, or seizures, which could have an adverse impact on our reputation and financial results. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, such as federal prosecution under the federal civil False Claims Act, if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management’s attention, result in substantial damage awards against us, and harm our reputation.

***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 the Zephyr Valve. 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 (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. 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 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 the FDA, which must become effective prior to commencing human clinical trials, and the 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, 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 (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 or regulatory authority 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 supplier 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 the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

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 or provider's competing clinical trial. 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.

***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 negatively affect our business, financial condition and results of operations.***

We are required to file various reports with the FDA and European regulators, including reports required by the MDRs that require that we report to the regulatory authorities if our solutions may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur and we have filed such reports in the past. 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 these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which will negatively affect our business, financial condition and results of operations.

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

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

***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.

***Healthcare reform measures could hinder or prevent the commercial success of our solutions.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that will harm our future revenues and profitability and the demand for our solutions. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payers 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. For example, the Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties. Although this tax has been suspended through 2019, it is expected to apply to sales of our products in 2020 and thereafter.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance and delaying the implementation of certain fees mandated by the Affordable Care Act. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and negatively affect our business, financial condition and results of operations.

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 CMS 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 2029 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS 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 current presidential administration and Congress may continue to pursue significant changes to the current healthcare laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may negatively affect our business, financial condition and results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may negatively affect our business, financial condition and results of operations.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare will harm:

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

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry.

***Legal, political and economic uncertainty surrounding the planned exit of the United Kingdom from the European Union may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the United Kingdom and pose additional risks to our business, financial condition and results of operations.***

Brexit, the departure of the United Kingdom from the European Union, is an imminent risk to Europe's economic stability. Discussions regarding the terms of the United Kingdom's exit have been ongoing and, on October 19, 2019, a withdrawal deal agreed with the European authorities was presented by the United Kingdom government to the British Parliament for approval. Instead, the British Parliament approved the granting of an additional period of time for it to review the terms and conditions of the withdrawal deal, obliging the government to request an extension to the European Union to avoid a no deal Brexit on October 31, 2019. Such extension has officially been granted by the European Union until January 31, 2020. Discussions between the European Union and the United Kingdom government and between the latter and the British Parliament are ongoing and it is uncertain when and on what terms the United Kingdom will depart from the European Union.

Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which European Union rules and regulations to replace or replicate in the event of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity, and restrict access to capital. In addition, depending on the terms of the United Kingdom's withdrawal from the European Union, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the United Kingdom and the European Union and, in particular, any arrangements for the United Kingdom to retain access to European Union markets either during a transitional period or more permanently.

***We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.***

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and, in the European Union and the EEA, GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, on June 28, 2018, California enacted the California Consumer Privacy Act (CCPA), which takes effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information.

The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, whether by us, one of our business associates or another third-party, could negatively affect our business, financial condition and results of operations, including but not limited to: investigation costs, material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

The privacy laws in the European Union have been significantly reformed. On May 25, 2018, the GDPR entered into force and became directly applicable in all European Union member states. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, require the appointment of data protection officers

when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the European Union, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the greater of €20 million or up to 4% of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation or adverse publicity, which could negatively affect our business, financial condition and results of operations.

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

***We face potential liability related to the privacy of health information we obtain.***

Most healthcare providers, including hospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient reimbursement support programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the European Union Data Protection Directive and legislation of the European Union member states implementing it.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Union into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information.

Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could negatively affect our business, financial condition and results of operations. If we or third-party contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing,

commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

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

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and internationally or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

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

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

## Risks Related to Our Intellectual Property

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

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell or export our products or to use our technologies or product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as patent trolls, have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or invitations to license, or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents. Because we have not conducted a formal freedom to operate analysis for patents related to our products, we may not be aware of issued patents that a third party might assert are infringed by one of our current products or future product candidates, which could materially impair our ability to commercialize our products or product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, we may not successfully find patents that our products or product candidates may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our products or product candidates.

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

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our 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 intellectual property to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- 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 or technologies that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement.

Any litigation or claim against us, even those without merit and even those where we prevail, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. 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) 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.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (USPTO) may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings, such as reexamination, inter parties review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued

patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent or other intellectual property infringement proceeding, a court may decide that a patent or other intellectual property of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question. Furthermore, even if our patents or other intellectual property are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents or other intellectual property at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

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

In order to remain competitive, we must develop, maintain and protect the proprietary aspects of our brands, technologies and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights by us and our current and future licensors. We, and our current and future licensors, may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

In addition, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology.

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

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents; any of our 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.

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

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized

use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

We also license rights to use certain proprietary information and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligations of the applicable license agreement between us and the owner. For example, the software we developed for the Chartis System includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rights in the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietary information and technology without having to adhere to a license agreement with the owner.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

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

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant

jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

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

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

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

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

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

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a first-to-invent system to a first-to-file system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to

technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may materially affect our business.

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

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors and have registered or applied to register these trademarks. We have not yet registered certain of our trademarks, including “CHARITE” in Germany, and as a result we sell certain products using names that may not be protected or may be subject to third party challenges for infringement of such third party’s trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

***Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies.***

Patents have a limited lifespan. In the United States, the standard patent term is typically 20 years after filing. Various extensions may be available. Even so, the life of a patent and the protection it affords are limited. As a result, our patent portfolio provides us with limited rights that may not last for a sufficient period of time to exclude others from commercializing products similar or identical to ours. For example, given the large amount of time required for the research, development, testing and regulatory review of implantable medical devices, patents protecting our products might expire before or shortly after they are commercialized.

Extensions of patent term may be available, but there is no guarantee that we would succeed in obtaining any particular extension-and no guarantee any such extension would confer patent term for a sufficient period of time to exclude others from commercializing products similar or identical to ours. In the United States, 35 U.S. Code § 156 Extension of patent term, permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). A patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval; only one patent may be extended; and extension is available for only those claims covering the approved device, a method for using it, or a method for manufacturing it. We have applied for such an extension however, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to any patents we obtain, or may grant more limited extensions than we request. An extension may not be granted or may be limited where there is, for example, a failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply before expiration of relevant patents, or some other failure to satisfy applicable requirements. If this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and

clinical trials along with our clinical and pre-clinical data. This could have a material adverse effect on our business and ability to achieve profitability.

### **Risks Related to This Offering and Ownership of Our Common Stock**

#### ***Our stock price may be volatile and the value of our common stock may decline.***

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

- actual or anticipated fluctuations in our financial condition and results of operations;
- variance in our financial performance from expectations of securities analysts or investors;
- changes in the pricing we offer our customers;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our solution;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- publicity associated with issues related to our solution;
- our involvement in litigation;
- future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- the trading volume of our common stock;
- changes in the anticipated future size and growth rate of our market;
- general economic, regulatory, and market conditions, including economic recessions or slowdowns;
- changes in the structure of healthcare payment systems; and
- developments or disputes concerning our intellectual property or other proprietary rights.

Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small expected public float of shares of our common stock on the Nasdaq Global Market, the trading market for our shares may be subject to increased volatility. In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future, which could result in substantial costs and divert our management's attention.

***There has been no prior market for our common stock. An active market may not develop or be sustainable and investors may not be able to resell their shares at or above the initial public offering price.***

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary from the



market price of our common stock following this offering. If you purchase shares of our common stock in this offering, you may not be able to resell those shares at or above the initial public offering price, if at all. An active or liquid market in our common stock may not develop after this offering or, if it does develop, it may not be sustainable.

***You will experience immediate and substantial dilution in the net tangible book value of the shares of common stock you purchase in this offering.***

The initial public offering price of our common stock will be substantially higher than the pro forma net tangible book value per share of our common stock immediately after this offering. If you purchase shares of our common stock in this offering, you will suffer immediate dilution of \$        per share, or \$        per share if the underwriters exercise their option to purchase additional shares in full, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to the sale of common stock in this offering and the initial public offering price of \$        per share. See “Dilution.” If outstanding options or warrants are exercised in the future, you will experience additional dilution.

***Future sales and issuances of our capital stock or rights to purchase capital stock could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline.***

We may issue additional securities following the closing of this offering. Future sales and issuances of our capital stock or rights to purchase our capital stock could result in substantial dilution to our existing stockholders. We may sell common stock, convertible securities, and other equity securities in one or more transactions at prices and in a manner as we may determine from time to time. If we sell any such securities in subsequent transactions, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock.

***We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.***

We will have broad discretion over the use of proceeds from this offering. Investors may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We currently intend to use the net proceeds from this offering for working capital and other general corporate purposes. Our failure to apply the net proceeds of this offering effectively could impair our ability to pursue our growth strategy or could require us to raise additional capital. In addition, pending their use, the proceeds of this offering may be placed in investments that do not produce income or that may lose value.

***Additional sales of our common stock by existing stockholders in the public market could cause the market price of our common stock to decline.***

Sales of a substantial number of shares of our common stock by existing stockholders in the public market following the completion of this offering, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Based on shares outstanding as of December 31, 2019, upon the closing of this offering, we will have outstanding a total of        shares of common stock, assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options or warrants, and after giving effect to the conversion of all outstanding shares of our preferred stock into shares of common stock immediately upon the closing of this offering. All of our executive officers and directors and substantially all of our other existing security holders are subject to lock-up agreements that restrict their ability to transfer shares of our common stock, stock options, and other securities convertible into, exchangeable for, or exercisable for our common stock during the period ending on, and including, the 180th day after the date of this prospectus, subject to certain limited exceptions. BofA Securities, Inc. and Morgan Stanley & Co. LLC may, in their discretion, permit our stockholders who are subject to these lock-up

agreements to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, all shares of common stock outstanding as of December 31, 2019 will become eligible for sale, of which 62,266,831 shares held by directors, executive officers, and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (Securities Act), and various vesting agreements.

In addition, as of December 31, 2019, there were 32,793,421 shares of common stock subject to outstanding options. We intend to register all of the shares of common stock issuable upon conversion of the shares of common stock issuable upon exercise of outstanding options, and upon exercise of settlement of any options or other equity incentives we may grant in the future, for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the lock-up agreements described above. The shares of common stock issuable upon conversion of these shares will become eligible for sale in the public market to the extent such options or warrants are exercised, subject to the lock-up agreements described above and compliance with applicable securities laws.

Holders of 184,166,734 shares of our common stock, including shares issuable upon the conversion of outstanding shares of preferred stock and shares of preferred stock issuable upon the exercise of outstanding warrants have rights, subject to some conditions, to require us to file registration statements for the public resale of the common stock issuable upon conversion of such shares or to include such shares in registration statements that we may file on our behalf or for other stockholders. See “Shares Eligible for Future Sale” and “Underwriting.”

***Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Based on our common stock outstanding as of December 31, 2019 and including the shares to be sold in this offering, upon the closing of this offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock will, in the aggregate, beneficially own approximately % of our outstanding common stock (assuming no exercise of the underwriters’ option to purchase additional shares of common stock). These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

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

Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business, or publish negative reports about our business, regardless of accuracy, our common stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We expect that only a limited number of analysts will cover our company following our initial public offering. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline.

Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or

investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

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

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

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and may be restricted by the terms of any then-current credit facility. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

***We are an “emerging growth company” and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (Section 404) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements. We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

***Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our consolidated 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 consolidated financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies.

***We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.***

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We expect such expenses to further increase after we are no longer an “emerging growth company.” The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, the senior members of our management team do not have significant experience with operating a public company. As a result, our management and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations

will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

***As a result of being 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.***

We will be required, pursuant to Section 404 to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company.” We have not yet commenced the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation required under Section 404, and we may not be able to complete our evaluation, testing, and any required remediation in a timely fashion once initiated. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to certify that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by the exchange on which our shares of common stock are listed, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***Anti-takeover provisions in our charter documents to be in effect upon the closing of this offering and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.***

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon the closing of this offering may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws will include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, or our chief executive officer;

- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into a number of classes, with each class serving staggered terms;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of a majority of our outstanding shares of common stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least a majority of our outstanding shares of common stock to amend our bylaws and certain provisions of our certificate of incorporation.

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, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

***Our amended and restated certificate of incorporation that will be in effect at the closing of this offering will provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States will be the exclusive forums 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 that will be in effect at the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for:

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

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation to be in effect upon the completion of this offering will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. Our stockholders cannot waive compliance with

the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificate of incorporation described in the preceding sentences. These exclusive-forum provisions 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 lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving the dispute in other jurisdictions. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If this ultimate adjudication were to occur, the federal district court exclusive forum provision in our amended and restated certificate of incorporation would no longer be contingent.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial condition, business strategy, plans, and objectives of management for future operations and statements that are necessarily dependent upon future events are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “target,” “should,” “will,” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. 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 risks described in the section titled “Risk Factors.” These risks are not exhaustive. Other sections of this prospectus include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those contained in, or implied by, any forward-looking statements.

You should not rely on these forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus or to conform these statements to actual results or to changes in our expectations, whether as a result of any new information, future events, changed circumstances or otherwise. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly those with COPD and emphysema;
- our expected future growth, including growth in international sales;
- our expected future growth of our sales and marketing organization;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- the rate and degree of market acceptance of our products;
- coverage and reimbursement for procedures performed using our products;
- the performance of third parties in connection with the development of our products, including third-party suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines;
- our plans to research, develop and commercialize our products and any other approved or cleared product;
- our ability to retain and hire our senior management and other highly qualified personnel;

- the development, regulatory approval, efficacy and commercialization of competing products;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our use of proceeds from this offering;
- our financial performance and capital requirements; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.



## INDUSTRY AND MARKET DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

## USE OF PROCEEDS

We estimate that the net proceeds to us from our issuance and sale of shares of our common stock in this offering will be approximately \$            million, or approximately \$            million if the underwriters exercise their option to purchase additional shares in full, based upon an assumed initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$            per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us from this offering by approximately \$            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. We may also increase or decrease the number of shares we are offering. A 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease the net proceeds to us from this offering by approximately \$            million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock and facilitate our future access to the capital markets. We currently intend to use the net proceeds from this offering as follows:

- approximately \$            million to hire additional sales and marketing personnel and expand marketing programs in the United States, Europe and Asia Pacific to promote the sales of Zephyr Valves;
- approximately \$            million to fund product development and research and development activities;
- in accordance with the terms of the Oxford Agreement and based on the amount drawn thereunder, to pay a success fee of \$1.9 million to Oxford on the completion of this offering; and
- the remaining proceeds for working capital and general corporate purposes, including acquisitions or strategic investments in complementary businesses or technologies, although we do not currently have any plans for any such acquisitions or investments.

The expected use of net proceeds from this offering represents our intentions based upon our present plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the growth of our business. Pending their use, we intend to invest the net proceeds of this offering in a variety of capital-preservation investments, including short- and intermediate-term, interest-bearing, investment-grade securities and U.S. government securities.

## **DIVIDEND POLICY**

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings for the operation and expansion of our business and, therefore, we do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in our current and future debt agreements and other factors that our board of directors may deem relevant. We are subject to covenants under our loan agreements that place restrictions on our ability to pay dividends.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2019:

- on an actual basis;
- on a pro forma basis to reflect (1) the automatic conversion of all shares of our convertible preferred stock outstanding as of December 31, 2019 and shares of our preferred stock to be issued as a result of the assumed exercise of the convertible preferred stock warrants per (3) below into 177,985,811 shares of our common stock immediately upon the closing of this offering; (2) the filing of our amended and restated certificate of incorporation in connection with and prior to the completion of this offering; (3) the assumed exercise of the convertible preferred stock warrants into 2,152,939 shares of our preferred stock for approximately \$2,275,657 resulting in the issuance of common stock and the related reclassification of the convertible preferred stock warrant liability to common stock and additional paid-in capital immediately prior to the closing of this offering; and (4) the payment of a \$1.9 million success fee to Oxford in accordance with the terms of the Oxford Agreement; and
- on a pro forma as adjusted basis to reflect (1) the pro forma items described immediately above and (2) the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting 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 initial public offering price and other terms of this offering determined at pricing. You should read this table together with “Use of Proceeds,” “Selected Consolidated Financial and Other Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

As of December 31, 2019

	Actual	Pro forma	Pro forma as Adjusted <sup>(1)</sup>
	(in thousands, except share and per share amounts)		
Cash and cash equivalents	\$	\$	\$
Term loan			
Convertible preferred stock warrant liability			
Convertible preferred stock, \$0.0001 par value per share; shares authorized, shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted			
Stockholders' (deficit) equity:			
Common stock, \$0.0001 par value per share; shares authorized, shares issued and outstanding, actual; shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital			
Accumulated other comprehensive loss			
Accumulated deficit			
Total stockholders' (deficit) equity	\$	\$	\$
Total capitalization	\$	\$	\$

(1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (the midpoint of the range set forth on the cover of this prospectus), would increase (decrease) the amount of each of cash and cash equivalents, working capital, total assets, total stockholders' (deficit) equity and total capitalization by \$ 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 underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase (decrease) the number of shares we are offering. Each increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by \$ million, assuming the assumed initial public offering price of \$ per share (the midpoint of the range set forth on the cover of this prospectus), remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of shares of our common stock that will be outstanding after this offering is based on 196,835,746 shares of common stock outstanding as of December 31, 2019, which includes 175,832,872 shares of common stock issuable upon the conversion of all of our outstanding shares of convertible preferred stock, and excludes:

- 32,793,421 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2019, at a weighted-average exercise price of \$0.17 per share;
- 2,152,939 shares of our preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2019 with an exercise price of \$1.057 per share, which warrants will expire on the earlier of (i) February 9, 2020 or (ii) the closing of this offering;
- 776,032 shares of our common stock reserved for issuance under our 2010 Stock Plan, which shares will cease to be available for issuance at the time our 2020 Equity Incentive Plan becomes effective;
- shares of our common stock reserved for future issuance pursuant to our 2020 Equity Incentive Plan, which will become effective prior to the completion of this offering and will include provisions that automatically increase the number of shares of common stock reserved for issuance thereunder each year;

- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective prior to the completion of this offering and will include provisions that automatically increase the number of shares of common stock reserved for issuance thereunder each year; and
- 4,155 shares of our common stock held as treasury stock.

## DILUTION

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

As of December 31, 2019, our historical net tangible book value was \$       million, or \$       per share of our common stock. Our historical net tangible book value represents our total tangible assets less our total liabilities. Our historical net tangible book value per share represents historical net tangible book value divided by the number of shares of our common stock outstanding as of December 31, 2019.

Our pro forma net tangible book value as of December 31, 2019 was \$       million, or \$       per share of common stock. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of shares of common stock outstanding as of December 31, 2019, after giving effect to the automatic conversion of all shares of convertible preferred stock outstanding as of December 31, 2019 into       shares of our common stock immediately upon the closing of this offering.

Our pro forma as adjusted net tangible book value represents our pro forma net tangible book value, plus the effect of the sale of shares of common stock in this offering at an assumed initial public offering price of \$       per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our pro forma as adjusted net tangible book value as of December 31, 2019 would have been \$       million, or \$       per share of our common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$       per share to our existing stockholders and an immediate dilution of \$       per share to investors participating in this offering. We determine dilution per share to investors participating in this offering by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by investors participating in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share		\$
Historical net tangible book value per share as of December 31, 2019	\$	
Increase (decrease) in historical net tangible book value per share attributable to conversion of our preferred stock		
Pro forma net tangible book value per share as of December 31, 2019	\$	
Increase in pro forma net tangible book value per share attributed to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after giving effect to this offering		
Dilution in pro forma as adjusted net tangible book value per share to new investors in this offering		\$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$       per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted net tangible book value per share by \$       per share and the dilution in pro forma as adjusted net tangible book value per share to new investors participating in this offering by \$       per share, 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. We may also increase or decrease the number of shares we are offering. A 1,000,000 share increase in the number of shares offered by us, as set forth on the cover page of

this prospectus, would increase the pro forma as adjusted net tangible book value per share by \$ [redacted] and decrease the dilution per share to investors participating in this offering by \$ [redacted], assuming the assumed initial public offering price of \$ [redacted] per share, which is the midpoint of the price range 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. A 1,000,000 share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by \$ [redacted] and increase the dilution per share to new investors participating in this offering by \$ [redacted], assuming the assumed initial public offering price of \$ [redacted] per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after estimated deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial offering price to public and other terms of this offering determined at pricing.

If the underwriters exercise their option in full to purchase [redacted] additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value of our common stock would increase to \$ [redacted] per share, representing an immediate increase to existing stockholders of \$ [redacted] per share and an immediate dilution of \$ [redacted] per share to investors participating in this offering, in each case, assuming the assumed initial public offering price of \$ [redacted] per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after estimated deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes as of December 31, 2019, on the pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration and the average price per share (1) paid to us by our existing stockholders and (2) to be paid by investors purchasing our common stock in this offering at an assumed initial public offering price of \$ [redacted] per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders					
New investors					
Total					

If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to [redacted] % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to [redacted] % of the total number of shares of our common stock outstanding after this offering.

The outstanding share information in the table above is based on 196,835,746 shares of our common stock outstanding as of December 31, 2019, which includes 175,832,872 shares of common stock issuable upon the conversion of all of our outstanding shares of convertible preferred stock, and excludes:

- 32,793,421 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2019, at a weighted-average exercise price of \$ 0.17 per share;
- 2,152,939 shares of our preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2019 with an exercise price of \$ 1.057 per share, which warrants will expire on the earlier of (i) February 9, 2020 or (ii) the closing of this offering;



- 776,032 shares of our common stock reserved for issuance under our 2010 Stock Plan, which shares will cease to be available for issuance at the time our 2020 Equity Incentive Plan becomes effective;
- shares of our common stock reserved for future issuance pursuant to our 2020 Equity Incentive Plan, which will become effective prior to the completion of this offering and will include provisions that automatically increase the number of shares of common stock reserved for issuance thereunder each year;
- shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective prior to the completion of this offering and will include provisions that automatically increase the number of shares of common stock reserved for issuance thereunder each year; and
- 4,155 shares of our common stock held as treasury stock.

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.

## SELECTED CONSOLIDATED FINANCIAL AND OTHER DATA

We have derived the consolidated statements of operations data for the years ended December 31, 2018 and 2019 and the consolidated balance sheet data as of December 31, 2018 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

When you read this selected consolidated financial and other data, it is important that you read it together with the historical consolidated financial statements and related notes to those statements, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included elsewhere in this prospectus.

	Years Ended December 31,	
	2018	2019
	(in thousands, except share and per share amounts)	
<b>Consolidated Statement of Operations Data:</b>		
Revenue	\$ 20,004	\$
Cost of goods sold	7,718	
Gross profit	12,286	
Operating expenses:		
Research and development	6,991	
Selling, general and administrative	20,347	
Total operating expenses	27,338	
Loss from operations	(15,052)	
Interest income	21	
Interest expense	(2,520)	
Other income (expense), net	(916)	
Net loss before tax	(18,467)	
Income tax expense	12	
Net loss	(18,479)	
Net loss per share attributable to common stockholders, basic and diluted <sup>(1)</sup>	\$ (1.10)	\$
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted <sup>(1)</sup>	16,748,545	
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) <sup>(1)</sup>		\$
Pro forma weighted-average shares outstanding, basic and diluted (unaudited) <sup>(1)</sup>		

(1) For an explanation of the method used to calculate our historical and pro forma basic and diluted net loss per share, and weighted average number of shares used in the computation of per share amounts, see Note 12 to our consolidated financial statements included elsewhere in the prospectus.

	As of December 31,	
	2018	2019
	(in thousands)	
<b>Consolidated Balance Sheet Data:</b>		
Cash and cash equivalents	\$	4,124
Working capital <sup>(1)</sup>		3,236
Total assets		15,013
Term loan		14,937
Convertible note payable to related party		18,668
Convertible preferred stock warrant liability		12
Total liabilities		41,804
Convertible preferred stock		140,535
Accumulated deficit		(189,800)
Total stockholders' (deficit) equity		(167,326)

(1) We define working capital as current assets less current liabilities. See our audited consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities as of December 31, 2018.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Consolidated Financial and Other Data" and our audited consolidated financial statements and related notes thereto included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this prospectus entitled "Risk Factors."

### Overview

We are a commercial-stage medical technology company that provides a minimally invasive treatment for patients with severe emphysema, a form of chronic obstructive pulmonary disease (COPD). Our solution, which is comprised of the Zephyr Endobronchial Valve (Zephyr Valve), the Chartis Pulmonary Assessment System (Chartis System) and the StratX Lung Analysis Platform (StratX Platform), is designed to treat severe emphysema patients who, despite medical management, are still profoundly symptomatic and either do not want or are ineligible for surgical approaches. We estimate our solution currently addresses approximately 500,000 patients in the United States and 700,000 patients in select international markets, which represents a global market opportunity of approximately \$12 billion.

We have a compelling body of clinical evidence with over 100 scientific articles published regarding the clinical benefits of Zephyr Valves, including in *The New England Journal of Medicine*, *The Lancet* and the *American Journal of Respiratory and Critical Care Medicine*. Multiple randomized controlled clinical trials have demonstrated that patients selected with the Chartis System and successfully treated with Zephyr Valves have shown statistically and clinically significant improvements in lung function, exercise capacity and quality of life compared to medical management alone.

In June 2018, we received pre-market approval (PMA) by the U.S. Food and Drug Administration (FDA) as a result of our breakthrough technology designation. The Zephyr Valve is now commercially available in more than 25 countries, with over 76,000 valves used to treat more than 19,000 patients through December 31, 2019. We have established reimbursement in major markets in North America, Europe and Asia Pacific and the Zephyr Valve has been included in treatment guidelines for COPD worldwide.

We market and sell our products in the United States, through a direct sales organization consisting of 32 sales territory managers. Our sales territory managers are focused on promoting awareness and increasing adoption of our solution primarily among the approximately 800 pulmonologists performing interventional pulmonary procedures and across approximately 500 high volume hospitals in the United States. We also have 26 sales territory managers outside the United States, with 18 in Europe and eight in Asia Pacific. We are expanding our commercial operations in the United States while continuing to foster our international growth. We employ both direct and distributor-based sales models, with over 90% of our revenue generated in markets where we sell directly.

In the United States, our solution is reimbursed based on established Category I Current Procedural Terminology (CPT) and ICD-10 Procedure Coding System (PCS) codes and associated MS-DRG and APC payment groupings. Current reimbursement in the United States is generally sufficient to cover the hospital costs of the procedure and related inpatient care. Commercial payors such as Aetna and Humana have issued positive coverage policies for the Zephyr Valve, and United Healthcare no longer considers the procedure unproven or experimental. Medicare covers our solution for patients when medically necessary, and other commercial insurers are approving pre-authorization requests on a case-by-case basis. Outside the United States, our solution is covered by major health systems across much of Europe, Australia and South Korea.

We manufacture all our products at our headquarters in Redwood City, California. This facility supports production and distribution operations, including manufacturing, quality control, raw material and finished goods storage. We have manufactured all our products at this facility for over ten years. We seek to maintain higher levels of inventory to protect ourselves from supply interruptions and have an established distribution system for both U.S. and international customers.

To date, we have financed our operations primarily through private placements of equity securities, debt financing arrangements and sales of our products. We have devoted substantially all of our resources to research and development activities related to our solution, including clinical and regulatory initiatives to obtain marketing approval, and sales and marketing activities. We generated revenue of \$ million, with a gross margin of % and a net loss of \$ million, for the year ended December 31, 2019 compared to revenue of \$20.0 million, with a gross margin of 61.4% and a net loss of \$18.5 million, for the year ended December 31, 2018. As of December 31, 2019, we had an accumulated deficit of \$ million, cash and cash equivalents of \$ million, and \$ million of outstanding term loans.

We have invested heavily in product development. Our research and development activities have been centered on driving continuous improvements to our solution. We have also made significant investments in clinical studies to demonstrate the safety and efficacy of the Zephyr Valve and to support regulatory submissions. We intend to make significant investments building our sales and marketing organization by increasing the number of sales territory managers and continuing our marketing efforts in existing and new markets throughout the United States, Europe and Asia Pacific. We also intend to continue to make investments in research and development efforts to develop our next generation products and support our future regulatory submissions for increasing our addressable market, expanded indications and new markets. 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.

The table below sets forth our revenue from U.S. and international sales over the past two years on a quarterly basis.

	Three Months Ended (unaudited)							
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
	(in millions)							
<b>Revenue from:</b>								
U.S. sales	\$ —	\$ —	\$ 0.1	\$ 0.5				
International sales	4.3	5.3	4.9	4.9				
Total revenue	<u>\$ 4.3</u>	<u>\$ 5.3</u>	<u>\$ 5.0</u>	<u>\$ 5.4</u>				

Our management has concluded, and in its report on our financial statements for the year ended December 31, 2018, our independent registered public accounting firm included an explanatory paragraph stating, that our recurring losses from operations and negative cash flows since inception and our need to raise additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. See “Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—Our history of recurring losses and anticipated expenditures raise substantial doubts about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.”

## **Factors Affecting our Business and Results of Operations**

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

### ***Our Ability to Recruit, Train and Retain Our Sales Force and its Productivity***

We have made, and intend to continue to make, significant investments in recruiting, training and retaining our direct sales force. This process requires significant education and training for our sales personnel to achieve the level of technical competency with our products that is expected by physicians and to gain experience building demand for our products. Upon completion of the training, our sales personnel typically require time in the field to grow their network of accounts and increase their productivity to the levels we expect. Successfully recruiting, training and retaining additional sales personnel will be required to achieve growth. In addition, inability to attract qualified sales personnel or the loss of any productive sales personnel would have a negative impact on our ability to grow our business. We currently have 32 sales territory managers in the United States and 26 sales territory managers outside the United States, with 18 in Europe and eight in Asia Pacific.

We have in the past and expect in the future to enter into different compensation arrangements with our sales professionals, which include minimum guaranteed commissions. This has impacted our compensation expenses in the past and we expect it will do so in the future.

### ***Physician, Patient and Hospital Awareness and Acceptance of Our Solution***

Our goal is to establish our solution as a standard of care for severe emphysema. We intend to continue to promote awareness of our solution through training and educating physicians, pulmonary rehabilitation centers, key opinion leaders and various medical societies on the proven clinical benefits of Zephyr Valves. 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 plan to continue building patient awareness through our direct-to-patient marketing initiatives, which include advertising, social media and online education. We also intend to continue helping physicians in their outreach to patients and other healthcare providers. These efforts require significant investment by our marketing and sales organization, and vary depending upon the physician's practice specialization, and personal preferences and geographic location of physicians, pulmonary rehabilitation centers and patients. In order to grow our business, we will need to continue to make significant investments in training and educating hospitals, physicians and patients on the advantages of our solution for the treatment of severe emphysema.

### ***Third-Party Reimbursement***

Since achieving regulatory approval in the United States in June 2018, we have launched the Zephyr Valve treatment and have made progress securing third-party payor reimbursement. The majority of our patients are Medicare beneficiaries. We estimate that roughly 75% of the potential Zephyr Valve patient population are Medicare/Medicaid beneficiaries, of which approximately 25% have managed Medicare/Medicaid and the remaining 50% have traditional Medicare/Medicaid. Approximately 25% of the potential Zephyr Valve patient population is under third-party commercial payor policies. A key element of our strategy remains to broaden our coverage by private third-party payor policies. As of December 31, 2019, commercial payors such as Aetna, Humana, Priority Health and Emblem Health have issued positive coverage policies for endobronchial valve procedures. United Healthcare removed the endobronchial valve codes from their non-covered list, and as such no longer considers the procedure unproven or experimental. Other commercial payors, such as many plans in the Blue Cross Blue Shield family of plans, do not yet consider our solution medically necessary, but these same plans are approving pre-authorization requests on a case-by-case basis. Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis and other commercial insurers not described above are approving pre-authorization requests on a case-by-case basis.

We have a dedicated patient reimbursement support team in the United States that works collaboratively with patients and providers to help secure the appropriate prior authorization approvals in advance of treatment. We continue to educate private insurers in the United States on our clinical data and patient selection tools in an effort to continue to expand the number of positive coverage policies, in order to increase our revenue. Outside the United States, our solution is covered by major health systems across much of Europe, Australia and South Korea.

### ***Competition***

Our industry is highly competitive and subject to rapid change from the introduction of new products and technologies and other activities of industry participants. Our goal is to establish our solution as a standard of care for severe emphysema. Existing treatments include medical management, lung volume reduction surgery (LVRS), lung transplantation as well as other minimally invasive treatments. Some of our competitors have several competitive advantages, including established relationships with pulmonologists who commonly treat patients with emphysema, significantly greater name recognition and significantly greater sales and marketing resources. In addition to competing for market share, we also compete against these companies for personnel, including qualified sales and other personnel that are necessary to grow our business. Certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. In addition to existing competitors, other companies may acquire or in-license competitive products and could directly compete with us. We must continue to successfully compete in light of our competitors' existing and future products and related pricing and their resources to successfully market to the physicians who use our products.

### ***Leveraging Our Manufacturing Capacity is Critical to Improving Our Gross Margin***

With our current operating model and infrastructure, we have the capacity to significantly increase our manufacturing production. If we grow our revenue and sell more units, our fixed manufacturing costs will be spread over more units, which we believe will reduce our manufacturing costs on a per-unit basis and in turn improve our gross margin. In addition, we intend to continue investing in manufacturing efficiencies in order to reduce our overall manufacturing costs. However, other factors will continue to impact our gross margins such as geographic mix, pricing and customer discounts, incentives, support services and potential seasonality.

### ***Investing in Research and Development to Foster Innovation to Expand Our Addressable Market***

We intend to continue investing in existing and next generation technologies to further improve our products and clinical outcomes, enhance patient selection and broaden the patient population that can be treated with our products. In addition, we are continuing to invest in the accuracy and features of our patient assessment tools. Moreover, we plan to conduct clinical research of AeriSeal, a potential product in development for the treatment of severe emphysema patients who are not qualified for Zephyr Valve treatment due to excessive collateral ventilation.

While research and development and clinical testing are time consuming and costly, we believe that a pipeline of new products and product enhancements that improve efficacy, safety and cost effectiveness is critical to increasing the adoption of our solution.

### ***Seasonality***

Historically, we have experienced seasonality outside of the United States, primarily in the first and third quarters and anticipate this trend to continue. In addition, as our sales grow in the United States, we may experience seasonality based on holidays, vacations and other factors because this is an elective procedure.

## **Components of Our Results of Operations**

### ***Revenue***

We currently derive all our revenue from the sale of our products to hospitals and distributors. We market and sell our products through a direct sales organization in the United States and through direct sales and several third-party distributors in select markets outside the United States. We currently generate most of our revenue from the sales of Zephyr Valves and delivery catheters. We also generate a smaller amount of our revenue from our Chartis System, which is comprised of sales of the balloon catheters, usage fees and sales of the Chartis console. The StratX Platform, while used to identify patients eligible for treatment with Zephyr Valves, does not independently generate any revenue for us. No single customer accounted for more than 10% of our revenue during the year ended December 31, 2018.

Revenue from sales of our products fluctuates based on volume of cases (procedures performed), the average number of Zephyr Valves used for a patient, pricing, discounts, incentives and mix of U.S. and international sales. Our revenue also fluctuates and in the future will continue to fluctuate from quarter-to-quarter due to a variety of factors, including the availability of reimbursement, the size and success of our sales force, the number of hospitals and physicians who are aware of and perform the procedures using our solution and seasonality. Our revenue from international sales may also be impacted by fluctuations in foreign currency exchange rates between the U.S. dollar (our reporting currency) and the local currency.

### ***Cost of Goods Sold and Gross Margin***

Cost of goods sold consists primarily of payroll and personnel-related expenses for our manufacturing and quality assurance employees, costs related to materials, components and subassemblies, third-party costs, manufacturing overhead, equipment depreciation, charges for excess, obsolete and non-sellable inventories. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision and management and an allocation facilities overhead cost, including rent and utilities. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as those incurred for shipping our products and costs related to providing analysis services for patient scans. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect cost of goods sold to increase in absolute dollars to the extent more of our products are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily by our manufacturing costs, pricing pressures and, to a lesser extent, the percentage of products we sell in the United States versus internationally and the percentage of products we sell to distributors versus directly to hospitals. Our gross margin is typically higher on products we sell directly to hospitals as compared to products we sell through distributors.

Our gross margin may increase over the long term to the extent our production volume increases as our fixed manufacturing costs would be spread over a larger number of units, thereby reducing our per-unit manufacturing costs. We expect our gross margin to fluctuate from period to period, however, based upon the factors described above and seasonality.

### ***Operating Expenses***

Our operating expenses have consisted solely of research and development costs and selling, general and administrative costs.

#### ***Research and Development Expenses***

Our research and development activities primarily consist of engineering and research programs associated with our products under development and improvements to our existing products. Research and development expenses



include payroll and personnel-related costs for our research and development employees, including, consulting services, clinical trial expenses, regulatory expenses, prototyping, testing, laboratory supplies, expenses related to stock-based compensation for employees engaged in research and development, and an allocation of facility overhead costs. Our clinical trial expenses include costs associated with clinical trial design, clinical trial site development and study costs, data management costs, related travel expenses, the cost of products used for clinical activities, and internal and external costs associated with our regulatory compliance. We expense research and development costs as they are incurred. We expect our research and development expenses, including related stock-based compensation expense, to increase in absolute dollars as we hire additional personnel to develop new product offerings and product enhancements.

#### *Selling, General and Administrative Expenses*

Our selling, general and administrative expenses consist of payroll and personnel-related costs for our sales and marketing personnel, including sales variable compensation, travel expenses, consulting, public relations costs, direct marketing, customer training, trade show and promotional expenses, stock-based compensation and allocated facility overhead costs, and for administrative personnel that support our general operations such as information technology, executive management, financial accounting, customer services and human resources personnel. We expense sales variable compensation at the time of the sale. Selling, general and administrative expenses also include costs attributable to professional fees for legal and accounting services, insurance, consulting fees, recruiting fees, travel expense, bad debt expense and depreciation.

We intend to continue to increase the size of our sales force and our marketing spending to generate sales opportunities. We expect our sales and marketing expenses to increase in absolute dollars as we hire additional sales personnel and increase our sales support infrastructure and add additional marketing programs in order to more fully penetrate the global opportunity. We also expect our administrative expenses, including stock-based compensation expense, to increase as we increase our headcount and expand our facility and information technology to support our operations as a public company. Additionally, we anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with being a public company, compliance with exchange listing and Securities and Exchange Commission (SEC) requirements, director and officer insurance premiums and investor relations costs. We also expect to see an increase in our stock-based compensation expense with the establishment of a new equity plan associated with this offering and related grants either in the form of restricted stock units or options. Our selling, general and administrative expenses may fluctuate from period to period due to the seasonality of our business and as we continue to add direct sales territory managers in new territories.

#### *Interest Expense and Income*

Interest expense consists primarily of interest expense related to our term loan facilities, including amortization of debt discount and issuance costs. We expect interest expense to decline in the near term because our convertible debt from Boston Scientific Corporation (BSC) converted into shares of our Series G-1 convertible preferred stock in April 2019. Accordingly, we anticipate having lower average outstanding principal and accrued interest balances. Interest income is predominantly derived from investing surplus cash.

#### *Other Income (Expense), Net*

Other income (expense), net primarily consists of changes in the fair value of our derivative liability, changes in the fair value of our outstanding convertible preferred stock warrants and foreign currency exchange gains and losses. We will continue to adjust the convertible preferred stock warrant liability for changes in fair value until the exercise or expiration of the warrants. We will continue to adjust the derivative liability for changes in fair value at each balance sheet date, with any changes in fair value recognized in the consolidated statement of operations and comprehensive loss.

## Results of Operations:

The following table summarizes our results of operations for the period indicated:

	Year Ended December 31, 2018
	(in thousands)
Revenue	\$ 20,004
Costs of goods sold	7,718
Gross profit	12,286
Operating expenses:	
Research and development	6,991
Selling, general and administrative	20,347
Total operating expenses	27,338
Loss from operations	(15,052)
Interest income	21
Interest expense	(2,520)
Other income (expense), net	(916)
Net loss before tax	(18,467)
Income tax expense	12
Net loss	\$ (18,479)

### Revenue

Revenue was \$20.0 million for the year ended December 31, 2018, which consisted of sales of products to hospitals and distributors. We generated revenue of \$19.4 million from sales of products in international markets and \$0.6 million from sale of products in the United States. We obtained FDA approval for the Zephyr Valves in the United States in June 2018 and began generating revenue in the United States in the third quarter of 2018.

### Cost of Goods Sold and Gross Margin

Cost of goods sold was \$7.7 million for the year ended December 31, 2018, which consisted of \$4.0 million of payroll and personnel-related expenses, including expenses related to stock-based compensation, for our manufacturing and quality assurance employees, \$1.2 million of materials costs, in relation to the manufacture of our products, \$1.1 million of allocated facilities costs, \$0.7 million of costs related to testing of our products, and the remainder associated with the costs of supplies, equipment depreciation, professional services and other expenses. Our gross margin for the year ended December 31, 2018 was 61.4%.

### Research and Development Expenses

Research and development expenses were \$7.0 million for the year ended December 31, 2018. Research and development expenses consisted of \$3.0 million of payroll and personnel-related expenses, including expenses related to stock-based compensation, for our research and product development employees, \$1.9 million of costs associated with our clinical trials, including fees paid to contract research organizations (CROs), \$0.9 million of consulting costs and the remainder associated with the costs of allocated overhead, travel, product testing and other expenses.

## ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses were \$20.3 million in the year ended December 31, 2018. Selling, general and administrative expenses consisted of \$12.9 million of payroll and personnel-related expenses, including expenses related to stock-based compensation, for our sales and administrative personnel, \$3.5 million of professional fees for legal, consulting, accounting, tax and other services, \$1.4 million of travel related expenses, \$1.4 million of facilities related expenses, including rent, equipment, depreciation, information technology costs and utilities, and the remainder for marketing and public relations, professional subscriptions and other general and administrative expenses.

## ***Interest Expense and Income***

Interest expense consists primarily of \$2.5 million of interest expense related to our term loan facilities, including amortization of debt discount and issuance costs, of which \$1.7 million related to a term loan and \$0.8 million related to the convertible note payable to a related party.

## ***Other Income (Expense), Net***

Other income (expense), net primarily consists of the change in derivative liability of \$0.6 million related to the success fee arrangement with Oxford Finance LLC (Oxford) and net foreign exchange losses of \$0.3 million.

## **Liquidity and Capital Resources; Plan of Operation**

To date, we have financed our operations primarily through private placements of equity securities, debt financing arrangements and sales of our products. As of December 31, 2018, we had cash and cash equivalents of \$4.1 million, an accumulated deficit of \$189.8 million and \$15 million and \$18 million outstanding under our loan and security agreements with Oxford and BSC, respectively. As of December 31, 2018, accrued interest on our loan and security agreements with Oxford and BSC was \$1.3 million and \$0.8 million, respectively.

### ***Oxford Term Loan***

In August 2014, we entered into the Loan and Security Agreement with Oxford (Oxford Agreement) for up to \$20.0 million in term loans and amended that agreement in May 2017 and twice in May 2018. In 2014, we borrowed \$15.0 million under Term Loan A and had the ability to draw the additional \$5.0 million under Term Loan B conditioned upon the achievement of a revenue milestone. The period during which we could draw an additional \$5.0 million ended on November 30, 2015 without us borrowing the additional \$5.0 million. The loan bears interest at 8.96%, which is equal to the sum of the three month U.S. LIBOR reported three business days prior to the funding date, and 8.72% and has a five-year term. The first 36 months were interest only payments followed by 24 months of equal payments of principal and interest. A final payment of 8.50% of the term loan amount is due at maturity and is being accreted using the effective interest rate method. The loan is collateralized by assets, including cash and cash equivalents, accounts receivable, intellectual property and equipment. We may prepay the loan, subject to certain requirements. The Oxford Agreement includes customary restrictive covenants, events of default and other customary terms and conditions.

In May 2017, we entered into a First Amendment to the Oxford Agreement that extended the interest only period through June 2018 and included an additional fee of \$0.1 million due upon maturity.

In May 2018, we entered into Second and Third Amendments to the Oxford Agreement that extended the interest only period through May 2019 and the maturity date to July 1, 2020. We had the option to further extend the interest only period through March 2020 and the maturity date to May 1, 2021, provided that no event of default has occurred. In May 2019, we exercised our option to further extend the interest only period through March 2020 and the maturity date to May 1, 2021. The loan bears interest at an annual rate equal to the greater of (i) 8.71% and (ii) the sum of (a) the greater of the one month U.S. LIBOR rate on the last business day of the month that immediately precedes the month in which the interest will accrued and 1.85% plus (b) 6.86%. The incremental amendment fee,

due at maturity, is \$0.4 million and was increased to \$0.8 million when we extended the interest only period through March 2020.

In connection with the original Oxford Agreement in August 2014, we also entered into the Success Fee Agreement. In the event of a sale or other disposition by us of all or substantially all of our assets, a merger or consolidation or an initial public offering (a Liquidity Event), before the termination of the agreement on August 28, 2021, we are required to pay up to \$2.5 million (Success Fee) to Oxford. The Success Fee is equal to \$1.25 million multiplied by the ratio of the principal amount of term loans outstanding to \$20.0 million (Ratio) if the Liquidity Event occurs within 18 months of August 28, 2014, \$1.75 million multiplied by the Ratio if the Liquidity Event occurs after 18 months and within three years of August 28, 2014, and \$2.5 million multiplied by the Ratio if the Liquidity Event occurs after the third anniversary of August 28, 2014. This agreement has been identified as a freestanding derivative under Financial Accounting Standards Board Accounting Standards Codification Topic 815 (ASC 815), and is remeasured to its fair value at the end of each reporting period and any change in fair value is recognized as change in fair value of derivative liability in the statement of operations and comprehensive loss. As of December 31, 2018, \$15.0 million principal amount of term loans was outstanding under the Oxford Agreement, such that the maximum amount of Success Fee subject to a potential payout was \$1.9 million. Based on the amount drawn under the Oxford Agreement as of the date hereof, we will be obligated to pay the success fee of \$1.9 million on the completion of this offering.

We incurred fees and legal expenses of \$0.1 million in connection with the Oxford Agreement and related Amendments, which are recorded as deferred financing costs and amortized to interest expense. We also paid \$0.2 million in fees to Oxford which is reflected as a discount on the debt and is being accreted over the life of the term loan. In 2018, we recorded interest expense related to deferred financing and debt issuance costs of less than \$0.1 million.

#### ***Loan and Security Agreement with BSC***

In May 2017, we entered into a Second Lien Loan and Security Agreement with BSC (BSC Agreement), for up to \$30.0 million in term loans. The loans under the BSC Agreement are subordinated to any indebtedness under the Oxford Agreement. Under the BSC Agreement, BSC agreed to make one or more term loans to us until the maturity date in May 2022. The principal amount outstanding under the term loans drawn prior to June 30, 2018 (Initial Term Loans) is interest free from the date of such term loan through and including June 30, 2018. Beginning on July 1, 2018, all outstanding term loans, and all subsequent term loans, accrue interest at a fixed rate of 8.96%. Interest accrues until such term loan is converted into our stock or paid in full. We may prepay the loan, subject to certain requirements. The BSC Agreement includes customary representations and warranties, restrictive covenants, events of default and other customary terms and conditions.

If we complete any Qualified Equity or Debt Financing or any Change of Control or Liquidation occurs (each term as defined in the BSC Agreement), outstanding principal and accrued interest on the loans are convertible at BSC's option into our stock. Subject to BSC's conversion rights, we have the option to prepay all of the term loans, at any time.

In conjunction with the BSC Agreement, we and BSC entered into a No Shop Agreement such that from the date of execution of the agreement through the earlier of ten days following receipt by BSC of a letter confirming our submission of the final module of our PMA application to the FDA and March 31, 2018, we would not sign a term sheet or engage in discussions to sell our company. The No Shop Agreement terminated in 2018.

In addition, BSC's Right of First Negotiation, originally received as part of BSC's investment in our Series F-1 Preferred Stock, was amended to shorten the period it has to exercise its Right of First Negotiation from ten to five business days, and to shorten the exclusive negotiation period from 75 to 45 days with respect to the initial notice from us that we intend to pursue a change in control or an initial public offering. For subsequent notices from us, BSC has ten days to exercise its right of first negotiation, and 75 days to enter into definitive agreements for a change in control transaction. We have provided an initial notice to BSC of our intention to pursue this initial public

offering and BSC has declined to exercise its Right of First Negotiation. BSC's Right of First Negotiation will terminate in connection with the completion of this offering.

We borrowed \$6.0 million in 2017, \$12.0 million in 2018 and \$6.0 million in January 2019 under the BSC Agreement.

We incurred fees and legal expenses of \$0.1 million in connection with the BSC Agreement, which are reported on the balance sheet as a direct deduction from the face amount of the convertible note. Amortization of the issuance costs are calculated using the effective interest rate method over the term of the note and recorded as a non-cash interest expense. In 2018, we recorded interest expense of \$0.8 million.

In April 2019, all outstanding indebtedness and accrued interest under the BSC Agreement converted into shares of our Series G-1 preferred stock. We retain the ability to draw up to an additional \$6.0 million under the BSC Agreement until the maturity date in May 2022, subject to customary conditions to borrowing including a bringdown of representations and warranties, compliance with restrictive covenants and that no event of default be ongoing.

### ***Funding Requirements***

We expect to incur continued expenditures in the future in support of our commercial infrastructure, sales force and other commercialization efforts. In addition, we intend to continue to make investments in the development of our products, including ongoing research and development programs. We also expect to incur additional costs associated with operating as a public company. Lastly, we may also undertake additional expenses to further expand our commercial organization and efforts, enhance our research and development efforts and pursue product expansion opportunities.

As of December 31, 2019, we had cash and cash equivalents of \$ . Based on our current planned operations, we expect that the anticipated proceeds of this offering, together with our cash and cash equivalents and available borrowings under the Oxford Agreement, will enable us to fund our operating expenses for at least 12 months from the date hereof. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Our management has concluded that our history of recurring losses and anticipated expenditures for operating and investing activities raise substantial doubt about our ability to continue as a going concern. See Note 1 to our consolidated financial statements appearing at the end of this prospectus for additional information on our conclusion. Similarly, the report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2018 included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. See "Risk Factors—Our history of recurring losses and anticipated expenditures raise substantial doubts about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations" for further information.

Because of the numerous risks and uncertainties associated with research, development and commercialization of medical devices, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the costs of commercialization activities related to commercializing our products in the United States and elsewhere, including expanding territories, increasing sales and marketing personnel, actual and anticipated product sales, marketing programs, manufacturing and distribution costs;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the research and development activities we intend to undertake, product enhancements that we intend to pursue;
- whether or not we pursue acquisitions or investments in businesses, products or technologies that are complementary to our current business;
- the degree and rate of market acceptance of our products in the United States and elsewhere;
- changes or fluctuations in our inventory supply needs and forecasts of our supply needs;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence of competing technologies or other adverse market developments.

Until such time, if ever, as we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and collaborations or licensing arrangements. There can be no assurance that our efforts to procure additional financing will be successful or that, if they are successful, the terms and conditions of such financing will be favorable to us or our stockholders. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through collaborations agreements, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses that may not be favorable to us. If we are unable to raise capital when needed, we will need to delay, limit, reduce or terminate planned commercialization or product development activities, or grant rights to develop and commercialize products or product candidates that we would otherwise prefer to develop and market ourselves in order to reduce costs.

### **Summary Statement of Cash Flows**

The following table sets forth the primary sources and uses of cash and cash equivalents for the period presented below:

	<b>Years Ended December 31,</b>
	<b>2018</b>
	<b>(in thousands)</b>
Net cash (used in) provided by:	
Operating activities	\$ (18,394)
Investing activities	200
Financing activities	12,114
Effect of exchange rate changes	154
Net increase (decrease) increase in cash and cash equivalents	<u>\$ (5,926)</u>

### **Cash Flows from Operating Activities**

Net cash used in operating activities was \$18.4 million for the year ended December 31, 2018. Cash used in operating activities was primarily a result of the net loss of \$18.5 million, an increase in accounts receivable of \$0.3

million, an increase in inventory of \$1.2 million, a decrease in accounts payable of \$0.6 million, a decrease in deferred tax liability of \$0.2 million, a decrease of \$0.1 million in deferred rent liability partially offset by, an increase in accrued and other liabilities of \$0.9 million, change in the fair value of the derivative liability of \$0.6 million, depreciation and amortization expense of \$0.3 million, stock-based compensation expense of \$0.4 million and write down of inventory due to obsolescence of \$0.3 million.

### **Cash Flows from Investing Activities**

Net cash provided by investing activities in the year ended December 31, 2018 was \$0.2 million primarily consisting of maturities of investments of \$0.5 million, offset by the purchases of property and equipment of \$0.3 million.

### **Cash Flows from Financing Activities**

Net cash provided by financing activities in the year ended December 31, 2018 of \$12.1 million primarily relates to proceeds of \$12.0 million from additional borrowings under the BSC Agreement and \$0.1 million proceeds from the exercise of stock options and preferred stock warrants.

### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of December 31, 2019:

	Payments Due by Period (in thousands)				Total
	Less than 1 year	1-3 years	3-5 years	More than 5 years	
Operating lease obligations <sup>(1)</sup>	\$	\$	\$	\$	\$
Long-term debt obligations <sup>(2)</sup>	\$	\$	\$	\$	\$

(1) We lease our laboratory and office facilities in Redwood City, California and Neuchâtel, Switzerland under non-cancelable operating leases with expiration dates in July 2025 and January 2021, respectively. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

(2) In August 2014, we borrowed \$15.0 million under the Oxford Agreement. In May 2018, we entered into amendment to the Oxford Agreement that extended the interest only period through May 2019 and the maturity date to July 1, 2020. In May 2019, we exercised our option to further extend the interest only period through March 2020 and the maturity date to May 1, 2021. In May 2017, we entered into the BSC Agreement for up to \$30.0 million in Convertible Promissory Notes that we can borrow in \$0.5 million (subject to a \$3.0 million minimum) or more amounts during the period beginning in May 2017 and ending on May 13, 2022, the Maturity Date. As of December 31, 2018, we had borrowed \$18.0 million. In January 2019, we borrowed \$6.0 million pursuant to the BSC Agreement. In April 2019, all Convertible Promissory Notes converted into shares of our Series G-1 convertible preferred stock.

We enter into contracts in the normal course of business with third-party contract organizations for pre-clinical studies and testing, manufacture and supply of our pre-clinical materials and providing other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

### **Off-Balance Sheet Arrangements**

Through December 31, 2018, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

### **Critical Accounting Policies, Significant Judgments and Use of Estimates**

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the

reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses incurred during the reporting periods. Our estimates are based on our knowledge of current events and actions we may undertake in the future and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may materially differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. For more detail on our critical accounting policies, refer to Note 2 to the financial statements appearing elsewhere in this prospectus.

### ***Revenue Recognition***

Our revenue is generated from the sale of our products to distributors and hospitals in the U.S. and international markets. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring the products. Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of our products to our customers, either upon shipment of the product or delivery of the products to the customer under the terms and conditions agreed with the customer. We defer revenue relating to any remaining performance obligations by us to the customer after delivery such as free products and free analysis services of patient scans to determine suitability of the patients for the treatment using the Zephyr Valves.

We identify performance obligations in contracts with customers, which may include our products and implied promises to provide free products and analysis services for patient scans. The transaction price is determined based on the amount expected to be entitled to in exchange for transferring the promised services or product to the customer. We are entitled to the total consideration for the products ordered by customers, net of early pay discounts, volume-based rebates and other transaction price adjustments. We exclude taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price. We accept product returns at our discretion or if the product is defective as manufactured. We elected to treat shipping and handling costs as a fulfillment cost and include them in the cost of goods sold as incurred.

### ***Inventories***

Inventories are valued at the lower of cost to purchase or manufacture the inventory or net realizable value. Cost is determined using the first-in, first-out method for all inventories. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. We record write-downs of inventories which are obsolete or in excess of anticipated demand or market value based on consideration of product lifecycle stage, technology trends, product development plans and assumptions about future demand and market conditions. Inventory write-downs are intended to reduce the carrying value of inventory to its net realizable value.

### ***Research and Development***

Research and development expenses consist of costs incurred to further our research and development activities and include compensation costs, stock-based compensation, engineering and research expenses, clinical trials and related expenses, regulatory expenses, manufacturing expenses incurred to build products for testing, allocated facilities costs, consulting fees and other expenses incurred to sustain our overall research and development programs. All research and development costs are expensed as incurred.

Clinical trial costs are a significant component of our research and development expenses. We have a history of contracting with third parties that perform various clinical trial activities on our behalf in the ongoing development of its product candidates. The financial terms of these contracts are subject to negotiations and may vary from contract to contract and may result in uneven payment flow. We accrue and expense costs of our clinical trial activities performed by third parties, including CROs and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. We determine these estimates through discussion with internal personnel and outside service providers as to progress or stage of



completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services.

### ***Convertible Preferred Stock***

We record all shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, in certain events considered not solely within our control, such as a merger, acquisition or sale of all or substantially all of our assets, each of which we refer to as a deemed liquidation event, the convertible preferred stock will become redeemable at the option of the holders of at least a majority of the then outstanding such shares. We have not adjusted the carrying values of the convertible preferred stock to its liquidation preference because a deemed liquidation event obligating us to pay the liquidation preferences to holders of shares of convertible preferred stock is not probable. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a deemed liquidation event will occur.

### ***Convertible Preferred Stock Warrants***

We have issued freestanding warrants to purchase shares of convertible preferred stock. We accounted for these warrants as a liability in our financial statements because the underlying instrument into which the warrants are exercisable contains deemed liquidation provisions that are outside our control. The warrants were recorded at fair value using an option pricing model based on an allocation of our aggregate value to the outstanding equity instruments, applying a discount to the warrant value for lack of marketability. The warrants were subject to remeasurement at each balance sheet date with any changes in fair value being recognized as a component of other income (expense), net in the statements of operations and comprehensive loss. We continued to adjust the liability for changes in fair value until the completion of our initial public offering, at which time the outstanding convertible preferred stock warrants might be exercised for shares of common stock and the related final fair value of the warrant liability will be reclassified to stockholders' deficit.

### ***Common Stock Valuation and Stock-Based Compensation***

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The grant date fair value of stock-based awards is expensed on a straight-line basis over the period during which the employee is required to provide service in exchange for the award, which is typically the vesting period. We account for forfeitures as they occur.

We account for stock options issued to non-employees based on the fair value of the stock options, using the Black-Scholes option pricing model, at the measurement date and is subject to periodic adjustments as the stock options vest and at the end of each reporting period and the resulting change in value, if any, is recognized in our statements of operations and comprehensive loss during the period the related services are rendered.

Estimates of the fair value of equity awards as of the grant date using valuation models such as the Black-Scholes option pricing model are affected by assumptions with a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately the amount of stock-based compensation expense recognized. These inputs are subjective and generally require significant analysis and judgment to develop. Changes in the following assumptions can materially affect the estimate of the fair value of stock-based compensation:

- *Expected Term.* The expected term is calculated using the simplified method, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the periods from grant until the mid-point for each of the tranches are averaged to provide an overall expected term.

- *Expected Volatility.* The expected volatility is derived from the average historical volatilities of publicly traded companies within our industry that we consider to be comparable to our business over a period approximately equal to the expected term for employees' options and the remaining contractual life for nonemployees' options. In evaluating similarity, we considered factors such as stage of development, risk profile, enterprise value and position within the life sciences industry.
- *Risk-free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.
- *Dividend Rate.* We assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.

#### *Common Stock Valuation*

The estimated fair value of the common stock underlying our stock options and stock awards was determined at each grant date by our board of directors, with input from management. All options to purchase shares of our common stock are intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant.

In the absence of a public trading market for our common stock, on each grant date, we develop an estimate of the fair value of our common stock based on the information known to us on the date of grant, upon a review of any recent events and their potential impact on the estimated fair value per share of the common stock, and in part on contemporaneous input from an independent third-party valuation firm.

Our valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (Practice Aid).

The assumptions used to determine the estimated fair value of our common stock are based on numerous objective and subjective factors, combined with management judgment, including:

- external market conditions affecting the pharmaceutical and medical devices industry and trends within the industry;
- our stage of development and business strategy;
- the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock;
- the prices at which we sold shares of our convertible preferred stock;
- our financial condition and operating results, including our levels of available capital resources;
- the progress of our research and development efforts;
- equity market conditions affecting comparable public companies; and
- general U.S. market conditions and the lack of marketability of our common stock.

For our valuations performed in August 2019, we applied the market approach outlined in the Practice Aid to determine our enterprise value. This approach relies on an analysis of publicly traded companies similar in industry or business model to us and uses these guideline companies to develop relevant market multiples and ratios. These multiples and ratios were then applied to our corresponding financial metrics.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

- *Option Pricing Method.* Under the option pricing method (OPM), shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Probability-Weighted Expected Return Method.* The probability-weighted expected return method is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

We determined that the OPM method was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Following the completion of this offering, our board of directors intends to determine the fair value of our common stock based on the closing sales price of our common stock on the date of grant of equity awards.

The intrinsic value of all outstanding options as of December 31, 2019 was approximately \$ \_\_\_\_\_ million, based on an assumed initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the estimated price range set forth on the cover of this prospectus), of which approximately \$ \_\_\_\_\_ million is related to vested options and approximately \$ \_\_\_\_\_ million is related to unvested options.

### ***Income Taxes***

Our major tax jurisdictions are the United States and California, Switzerland and Neuchâtel, and Grand Cayman.

We provide for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities arise due to differences between when assets or liabilities are recognized for tax purposes and when they are recognized for financial reporting purposes. Net operating losses and credit carryforwards are also deferred tax assets. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. All of our tax years will remain open for examination by the federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credits. We do not have any tax audits or other issues pending.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to annual limitations due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended (Code), as defined in Section 382, and other similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

The 2017 Tax Cut and Jobs Act included the implementation of a modified territorial tax system, which has the effect of subjecting earnings of our foreign subsidiaries to U.S. taxation on Global Intangible Low-Taxed Income (GILTI). The Financial Accounting Standards Board (FASB) allows companies to adopt a policy election to account for the tax on GILTI under one of two methods: (i) account for the tax on GILTI as a component of tax expense in the period in which the tax is incurred (the period cost method) or (ii) account for the tax on GILTI in a company's measurement of deferred taxes (the deferred method). We have elected to account for the tax on GILTI under the period cost method.

### **JOBS Act Accounting Election**

The Jumpstart Our Business Startups Act of 2012 (JOBS Act) permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act. 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, which may make comparison of our financials to those of other public companies more difficult.

### **Recent Accounting Pronouncements**

See "Recent Accounting Pronouncements" in Note 3 to our consolidated financial statements included elsewhere in this prospectus for additional information.

### **Quantitative and Qualitative Disclosures about Market Risk**

#### ***Interest Rate Risk***

We are exposed to interest rate risks related to our cash, cash equivalents and borrowings. We had cash and cash equivalents of \$4.1 million as of December 31, 2018, which consist of cash and money market funds. We held cash in foreign banks of approximately \$2.2 million at December 31, 2018 that was not federally insured. Interest-earning money market funds carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

We had outstanding debt of \$33.6 million as of December 31, 2018, with interest rates ranging from 8.96- 9.17%. In the ordinary course of business, we may enter into contractual arrangements to reduce our exposure to interest rate risks. We believe that a 10% change in interest rates would not have a significant impact on our consolidated financial statements.

#### ***Foreign Currency Exchange Risk***

We operate in countries other than the United States, and, therefore, we are exposed to foreign currency risks. Revenue from sales outside of the United States represented 97.2% of our total revenue for the year ended December 31, 2018. We bill most direct sales outside of the United States in local currencies, which are mostly comprised of the Swiss franc, the euro, the British pound, and the Australian dollar. Operating expenses related to these sales are largely denominated in the same respective currency, thereby limiting our transaction risk exposure. We therefore believe that the risk of a significant impact on our operating income from foreign currency fluctuations is not significant. The risk of a significant impact on our operating income from foreign currency fluctuations will further diminish as revenue from sales to customers in the United States increases and represents a greater proportion of total revenues. A 10% change in weighted average foreign currency exchange rates would have changed our revenues and operating expenses for the year ended December 31, 2018 by approximately \$2.0 million

and \$1.2 million, respectively, with a net impact of \$0.8 million on our net income. We do not currently hedge our exposure to foreign currency exchange rate fluctuations; however, we may choose to hedge our exposure in the future.

**Overview**

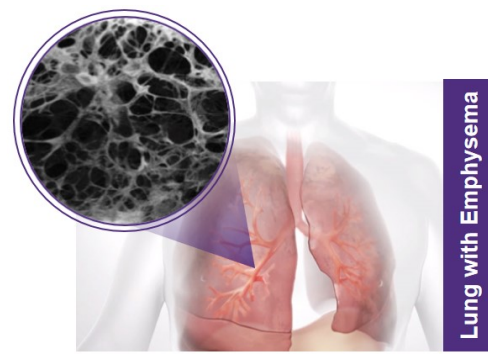
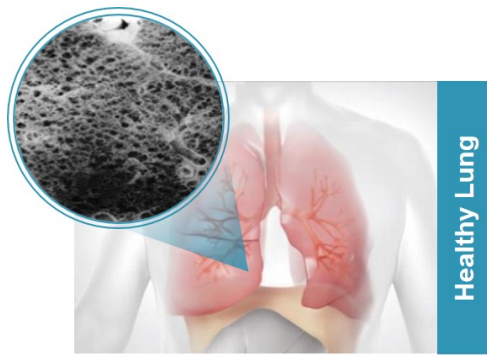
We are a commercial-stage medical technology company that provides a minimally invasive treatment for patients with severe emphysema, a form of chronic obstructive pulmonary disease (COPD). Our solution, which is comprised of the Zephyr Endobronchial Valve (Zephyr Valve), the Chartis Pulmonary Assessment System (Chartis System) and the StratX Lung Analysis Platform (StratX Platform), is designed to treat severe emphysema patients who, despite medical management, are still profoundly symptomatic and either do not want or are ineligible for surgical approaches. We estimate our solution currently addresses approximately 500,000 patients in the United States and 700,000 patients in select international markets, which represents a global market opportunity of approximately \$12 billion.

We have a compelling body of clinical evidence with over 100 scientific articles published regarding the clinical benefits of Zephyr Valves, including in *The New England Journal of Medicine*, *The Lancet* and the *American Journal of Respiratory and Critical Care Medicine*. Multiple randomized controlled clinical trials have demonstrated that patients selected with the Chartis System and successfully treated with Zephyr Valves have shown statistically and clinically significant improvements in lung function, exercise capacity and quality of life compared to medical management alone.

In June 2018, we received pre-market approval (PMA) by the U.S. Food and Drug Administration (FDA) as a result of our breakthrough technology designation. The Zephyr Valve is now commercially available in more than 25 countries, with over 76,000 valves used to treat more than 19,000 patients through December 31, 2019. We have established reimbursement in major markets in North America, Europe and Asia Pacific and the Zephyr Valve has been included in treatment guidelines for COPD worldwide.

COPD refers to a group of lung diseases characterized by obstruction of airflow that interferes with normal breathing. In 2015, it affected approximately 175 million patients and was responsible for 3.2 million deaths globally. We estimate that there are approximately 8.5 million severe COPD patients in developed markets globally as of 2019. Of these approximately 8.5 million severe COPD patients, we estimate approximately 3.2 million have severe emphysema and approximately 5 million have severe chronic bronchitis. Of the approximately 3.2 million severe emphysema patients, we estimate that approximately 1.2 million may be eligible for treatment with Zephyr Valves, and an additional number may be able to be treated in the future with other technologies under development by us.

In the United States, COPD is the third leading cause of death and affected approximately 16 million Americans as of 2013. COPD is expected to be associated with approximately \$49 billion in direct medical costs in 2020. Emphysema, a form of COPD, which accounts for approximately 25% of all COPD patients, is a debilitating and life-threatening disease that progressively destroys lung tissue, resulting in a diminishing ability to breathe and engage in the most basic daily activities, leading to a high mortality rate. The lung damage caused by emphysema is irreversible. As of 2018, approximately 3.8 million patients in the United States were diagnosed with emphysema, of which roughly 1.5 million have severe emphysema. Of these 1.5 million severe emphysema patients, we estimate that approximately 500,000 patients would qualify for treatment with our Zephyr Valves, and an additional number may be able to be treated in the future with other technologies under development by us if successfully developed and approved.



There are several treatment options for patients with emphysema, depending on the level of severity of the disease, ranging from medical management to more invasive surgical options. However, these treatment options have significant limitations for patients with severe emphysema.

Initial treatment for emphysema is generally limited to medications that primarily target airway obstruction and reduce inflammation, but do not address the underlying lung tissue destruction. As the disease worsens, symptoms increase despite optimized drug therapy, pulmonary rehabilitation exercises and supplemental oxygen.

As patients enter the severe phase, many become increasingly unable to engage in the most basic daily activities as a result of the persistent feeling of breathlessness and this reduces their overall health status each year. At this point, physicians may refer patients to thoracic surgeons for single or double lung transplantation or for lung volume reduction surgery (LVRS), in which hyperinflated tissue is cut away and removed. These invasive surgical procedures involve substantial risk of complications, prolonged hospital stays and high mortality. In addition, many patients do not qualify for these procedures. Patients with severe emphysema generally experience a worse quality of life than patients with lung cancer. We believe there is both an urgent clinical need and a strong market opportunity for a solution that is safe, effective and minimally invasive.

Our solution, which is comprised of the Zephyr Valve, Chartis System and StratX Platform, is designed to address the need for a more effective, minimally invasive treatment option for patients with severe emphysema, offering bronchoscopic lung volume reduction without surgery and its associated risks. Zephyr Valves are indicated for bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. During the one-time bronchoscopic procedure, Zephyr Valves are placed in the airways to occlude the most diseased parts of the lung, allowing trapped air to escape until the lobe is reduced in size. The intended result is a reduction in lung volume and hyperinflation in the targeted lobe, allowing healthier parts of the lung to expand and take in more air. Patients who are successfully treated with the Zephyr Valve report improved breathing and the ability to go back to doing everyday tasks more easily.

We believe our solution provides the following important benefits:

- **Significant, durable improvements in lung function, exercise capacity and quality of life**, demonstrated in a substantial body of clinical data;
- **Well-characterized safety profile**, evidenced by the inclusion in global treatment recommendations and more than 19,000 patients treated globally with the Zephyr Valve;
- **High procedural success** driven by innovative and effective patient assessment tools; and
- **Minimally invasive procedure** typically lasting less than an hour.

Over 100 scientific articles have been published regarding the clinical benefits of Zephyr Valves, including multiple meta-analyses, review articles, cost-effectiveness analyses and risk-benefit analyses. The Zephyr Valve showed statistically significant improvements in lung function, exercise capacity and quality of life when compared to medical management alone in multiple randomized controlled clinical trials. Additionally, independent studies have demonstrated that Zephyr Valves deliver increases in the BODE Index (a multi-dimensional health status scoring system for patients with COPD) that have been associated with survival benefits.

The LIBERATE study, our pivotal study published in 2018, was a multicenter, multinational, randomized controlled clinical trial of Zephyr Valves that included 190 patients with severe emphysema and little to no collateral ventilation. All primary and secondary endpoints were statistically significant, including the proportion of patients achieving a clinically significant improvement in lung function as well as the mean improvements in exercise capacity, hyperinflation and quality of life. These outcomes were the result of a high rate of procedural success, with 84% of patients achieving a clinically meaningful reduction in treated lobe volume.

We market and sell our products in the United States through a direct sales organization consisting of 32 sales territory managers. Our sales territory managers are focused on promoting awareness and increasing adoption of our solution primarily among the approximately 800 pulmonologists performing interventional pulmonary procedures and across approximately 500 high volume hospitals in the United States. We currently have 26 sales territory managers outside the United States, with 18 in Europe and eight in Asia Pacific. We are expanding our commercial operations in the United States while continuing to foster our international growth. In international markets, we employ both direct and distributor-based sales models, with over 90% of our revenue generated in markets where we sell directly.

In the United States, our solution is reimbursed based on established Category I CPT and ICD-10 Procedure Coding System (PCS) codes and associated MS-DRG and APC payment groupings. Current reimbursement in the United States is generally sufficient to cover the hospital costs of the procedure and related inpatient care. As of December 31, 2019, commercial payors such as Aetna, Humana, Priority Health and Emblem Health have issued positive coverage policies for endobronchial valve procedures. United Healthcare removed the endobronchial valve codes from their non-covered list, and as such no longer considers the procedure unproven or experimental. Other commercial payors, such as many plans in the Blue Cross Blue Shield family of plans, do not yet consider our solution medically necessary, but these same plans are approving pre-authorization requests on a case-by-case basis. Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis and other commercial insurers not described above are approving pre-authorization requests on a case-by-case basis. Outside the United States, our solution is covered by major health systems across much of Europe, Australia and South Korea.

We generated revenue of \$ \_\_\_\_\_ million, with a gross margin of \_\_\_\_\_ % and a net loss of \$ \_\_\_\_\_ million, for the year ended December 31, 2019 compared to revenue of \$ 20.0 million, with a gross margin of 61.4 % and a net loss of \$18.5 million, for the year ended December 31, 2018. As of December 31, 2019, we had an accumulated deficit of \$ \_\_\_\_\_ million. We currently generate most of our revenue from the sales of Zephyr Valves and delivery catheters. We also generate a smaller amount of our revenue from our Chartis System, which is comprised of sales of the balloon catheters, usage fees and sales of the Chartis console. The StratX Platform, while used to identify patients eligible for treatment with Zephyr Valves, does not independently generate any revenue for us.

## Our Success Factors

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

- ***Innovative, minimally invasive treatment paired with proprietary patient selection technology.*** We have developed the first FDA-approved implant, the Zephyr Valve, to reduce hyperinflation associated with severe emphysema, which received a breakthrough technology designation and pre-market approval. To enhance optimal outcomes with the Zephyr Valve, the Chartis System and the StratX Platform are designed to help physicians identify and treat those patients most likely to benefit from treatment with Zephyr Valves. We



believe the combination of our innovative valve treatment and patient assessment tools represents a significant competitive advantage and our goal is to establish our solution as a standard of care for severe emphysema.

- **Addressing a large underserved market.** We are addressing a large underserved market for patients with severe emphysema whose treatment options are limited. We believe our solution currently addresses approximately 500,000 patients in the United States and 700,000 patients in select international markets who have severe emphysema with hyperinflation and limited to no collateral ventilation, representing an approximately \$12 billion global market opportunity. We have established significant momentum with our broad global commercial footprint across more than 25 countries and with a track record of more than 19,000 patients treated. Additionally, we have ongoing research and development efforts to further expand the addressable market of our products.
- **Compelling body of clinical evidence and inclusion in COPD guidance documents.** The safety, effectiveness and clinical advantages of Zephyr Valves have been demonstrated in multiple randomized controlled clinical trials. The quality of evidence for treatment with endobronchial valves has been graded “A” by the Global Initiative for Chronic Obstructive Lung Disease (GOLD), and the United Kingdom’s National Institute for Health and Care Excellence (NICE) has included this treatment as part of standard measures for COPD and recommended all qualifying patients be evaluated for eligibility. Treatment with endobronchial valves has been included in other national and international COPD guidance documents and evidence reviews, including organizations such as the German Respiratory Society (DGP), the Dutch National Health Care Institute (Zorginstituut Nederland), the Cochrane Library and the COPD Pocket Consultant Guide.
- **Favorable coverage and established reimbursement.** In the United States, our solution is reimbursed based on established Category I Current Procedural Terminology (CPT) and ICD-10 PCS codes and associated MS-DRG and APC payment groupings. Current reimbursement in the United States is generally sufficient to cover the hospital costs of the procedure and related inpatient care. As of December 31, 2019, commercial payors such as Aetna, Humana, Priority Health and Emblem Health have issued positive coverage policies for endobronchial valve procedures. United Healthcare removed the endobronchial valve codes from their non-covered list, and, as such, no longer considers the procedure unproven or experimental. Other commercial payors, such as many plans in the Blue Cross Blue Shield family of plans, do not yet consider our solution medically necessary, but these same plans are approving pre-authorization requests on a case-by-case basis. Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis. We estimate that roughly 75% of the potential Zephyr Valve patient population are Medicare/Medicaid beneficiaries, of which approximately 25% have managed Medicare/Medicaid and the remaining 50% have traditional Medicare/Medicaid. Approximately 25% of potential Zephyr Valve patient population is under third-party commercial payor policies. We have a dedicated patient reimbursement support team designed to assist patients as they navigate the reimbursement process that works collaboratively with patients and providers to help secure the appropriate prior authorization approvals in advance of treatment. We continue to educate private insurers on our clinical data and patient selection tools to continue to expand the number of positive coverage policies. Outside the United States, our solution is covered by major health systems across much of Europe, Australia and South Korea.
- **Comprehensive approach to market development and patient engagement.** We have established a stepwise approach to market development across three key stakeholders in severe emphysema treatment: hospitals, physicians and patients. Our commercial organization is focused on working with pulmonary physicians and their hospitals to build emphysema centers of excellence where physicians are instructed in the workup of advanced COPD and perform bronchoscopic lung volume reduction using our solution. Our team works closely with all members of the hospital care team to help these centers efficiently incorporate our solution as a new service line. In addition, we are partnering with these centers to build awareness and referrals from primary care and other physicians who may be managing severe emphysema patients in the community. We build upon this approach with direct-to-patient marketing initiatives that help educate patients on the Zephyr Valve procedure and where it is available. We believe that this comprehensive approach to engagement across multiple constituents will help to increase awareness of and demand for our solution.

- **Robust intellectual property portfolio.** We own intellectual property that covers the Zephyr Valve and Chartis System. As of December 31, 2019, we held 37 U.S. patents and 82 international patents that include device, apparatus and method claims. In addition, we believe that our trade secrets, including manufacturing know-how, provide additional barriers to entry.

## Our Growth Strategy

Our vision is to be a global leader in treating advanced lung disease and to have a transformational impact on the lives of patients. Our goal is to establish our solutions as the standard of care for the assessment and treatment of patients with severe COPD.

Key elements of our strategy to achieve this vision include:

- **Expanding our commercial organization in the United States to drive adoption of Zephyr Valves.** We currently sell Zephyr Valves to more than 80 hospitals and have 32 sales territory managers in the United States. We plan to expand our commercial organization by recruiting and training talented sales territory managers in existing and new markets in the United States to help facilitate further adoption and broaden awareness of Zephyr Valves primarily among the approximately 800 pulmonologists performing interventional pulmonary procedures across approximately 500 high volume hospitals. 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 solution and increase revenue growth.
- **Collaborating with hospitals to address unmet patient needs.** Our strategy is to identify regions with high unmet need, identify leading hospitals and work with champions of our solution to build emphysema centers of excellence. We believe there is a significant growth opportunity for hospitals to provide high quality comprehensive diagnosis and treatment for severe emphysema patients. We believe we can efficiently serve the United States market, focusing on approximately 500 high volume hospitals, of which we currently cover a small percentage.
- **Promoting awareness among patients, physicians and other healthcare providers.** We intend to continue to promote awareness of our solution through training and educating patients, physicians, pulmonary rehabilitation centers, key opinion leaders and various medical societies on the proven clinical benefits of Zephyr Valves. We also intend to continue helping physicians in their outreach to patients and other healthcare providers. 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 believe that many patients who suffer from severe emphysema are eager for a minimally invasive treatment option such as the Zephyr Valve. In a 2019 published study, we conducted a survey of 294 severe emphysema patients, of which 76.4% said they would choose a minimally invasive treatment option such as the Zephyr Valve over their existing treatment options. We also plan to continue building patient awareness through our direct-to-patient marketing initiatives, which include advertising, social media and online education. We also intend to continue helping physicians in their outreach to patients and other healthcare providers.
- **Continuing to invest in research and development to foster innovation and expand our addressable market.** Our commitment to improving patient lives fuels our desire to foster innovation through continuous research and product development. We intend to continue investing in existing and next generation technologies to further improve our products and clinical outcomes, enhance patient selection and broaden the patient population that can be treated with our products. We are in discussions with the FDA regarding the potential use of Zephyr Valves for the management of persistent air leaks (air leaks lasting five days or longer despite use of a chest tube). In addition, we are continuing to invest in the accuracy and features of our patient assessment tools. In the future, we also plan to conduct clinical research of AeriSeal, a potential product in development for the treatment of severe emphysema patients who are not qualified for Zephyr Valve treatment due to collateral ventilation.

- **Expanding in existing and new international markets** . We have established a leading international sales force in interventional pulmonology. We intend to continue expanding our team and seeking additional international regulatory clearances in order to more fully penetrate this global opportunity. As of December 31 , 2019, we have 26 sales territory managers outside the United States, with 18 in Europe and eight in Asia Pacific. Our goal is to further increase sales of the Zephyr Valves in existing international markets in Europe—including Austria, France, Germany, Italy, the Netherlands, Spain, Switzerland and the United Kingdom, deepen penetration in Australia, China and South Korea, 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.
- **Driving profitability by scaling our business operations to achieve cost and production efficiencies**. We plan to drive profitability and gross margin expansion by leveraging our manufacturing capacity to scale production volume, improve efficiencies and lower costs as we increase supply to meet the anticipated growing demands for our products. In the future, our goal is to lower the cost of goods sold through productivity improvements, implementation of lean manufacturing and spreading the fixed costs over increased number of units as we grow the volume of products sold.

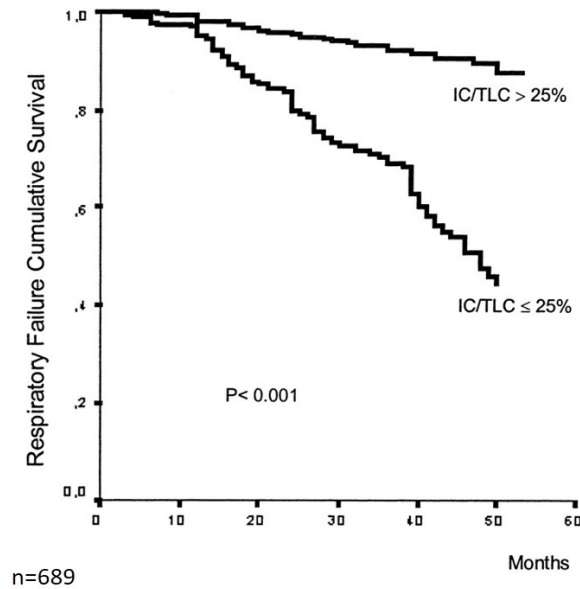
## **Our Market Opportunity**

### **Overview of COPD and Emphysema**

COPD refers to a group of lung diseases characterized by obstruction of airflow that interferes with normal breathing. Risk factors for COPD include smoking, environmental hazards, air pollution and genetics. In 2010, COPD accounted for approximately \$30 billion in direct medical expense in the United States alone, and COPD is expected to be associated with approximately \$49 billion in direct medical costs in 2020. COPD is the third leading cause of death in the United States, and one of the only major causes of death that continues to grow in developed countries. In 2015, 3.2 million people died from COPD worldwide, up almost 12% from 1990. In developed countries from 1990 to 2015, COPD-related deaths increased at a rate of almost 32%. The number of COPD patients continues to grow as Medicare estimates its number of COPD patients grew from 4.8 million in 2007 to 6.4 million in 2017.

Emphysema, a form of COPD, which accounts for approximately 25% of all COPD patients, is a debilitating and life-threatening disease that progressively destroys lung tissue, resulting in a diminishing ability to breathe and engage in the most basic daily activities, leading to a high mortality rate. The lung damage caused by emphysema is irreversible. In patients with emphysema, diseased portions of the lung lose their ability to exchange oxygen and carbon dioxide due to damage to the air sacs, or alveoli. The diseased portions of the lung also lose elasticity, become over-inflated, and crowd out the healthier lung tissue. As a result, patients with emphysema experience shortness of breath, gradually losing their ability to engage in the most basic daily activities such as climbing a flight of stairs, walking or showering. Based on published literature, the five-year mortality rate for patients with severe emphysema is approximately 50%.

The following graph shows an increased mortality rate for patients with more hyperinflation relative to patients with less hyperinflation.



The inspiratory capacity-to-total-lung capacity (IC/TLC) ratio is an indirect measurement of lung hyperinflation. The graph above depicts two Kaplan-Meier survival analyses of (1) patients with an IC/TLC ratio greater than 25% and (2) patients with an IC/TLC less than or equal to 25%.

Emphysema is diagnosed through a combination of breathing tests and computed tomography (CT) imaging of the lungs. The diagnosis is typically done by a radiologist or a pulmonologist. Emphysema severity is evaluated using a standardized test called spirometry as well as the degree of patient symptoms.

#### ***Current Treatments for Emphysema and Their Limitations***

There are several treatment options for patients with emphysema, depending on the level of severity of the disease, ranging from medical management to surgery. However, these treatment alternatives have significant limitations and in some cases are highly invasive.

Initial treatment for emphysema is generally limited to prescribing inhaled medications such as drugs that open the airways and reduce inflammation, which primarily target airway obstruction. However, as the disease becomes more severe, the effectiveness of drug therapy is diminished, and patients feel increasingly breathless. As the disease progresses, physicians may prescribe pulmonary rehabilitation exercises and supplemental oxygen, but these can be poorly tolerated by patients and often lose effectiveness with time. As patients enter the severe phase, many become increasingly unable to engage in the most basic daily activities as a result of the persistent feeling of breathlessness and this reduces their overall health status each year. At this point, physicians may refer patients to thoracic surgeons for LVRS, in which hyperinflated tissue is cut away and removed, or for single or double lung transplantation.

LVRS is an invasive surgery that involves cutting away diseased tissue to create space for the remaining lung to more fully inflate. LVRS was studied extensively in the National Emphysema Treatment Trial (NETT), which showed that while a broad group of patients gained quality of life and exercise capacity from the surgery, it also involved substantial risks of complications, prolonged hospital stays and even death. As a result of the NETT study, use of LVRS was restricted by the Centers for Medicare & Medicaid Services (CMS) to a subgroup of patients and can only be offered at a limited number of highly specialized medical centers.

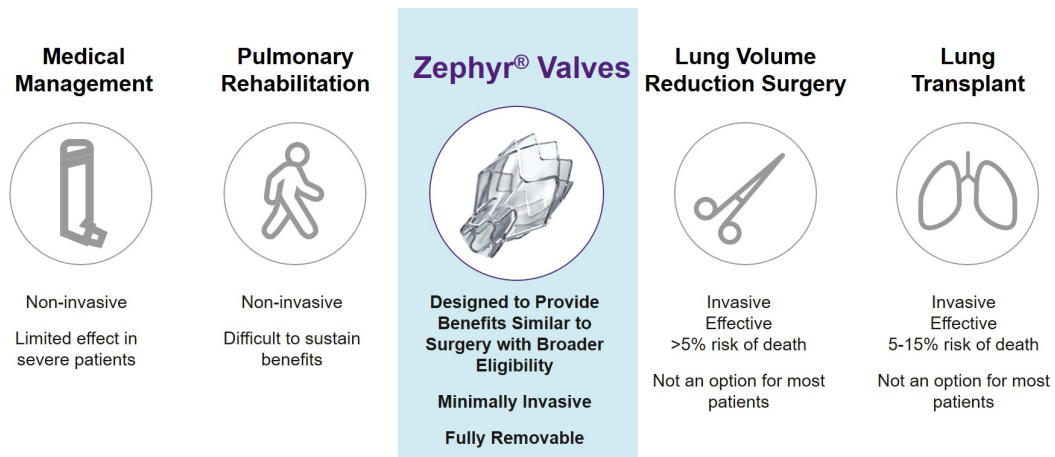
Lung transplantation involves surgically removing one or both lungs and replacing them with donor lungs. This procedure is highly time and resource intensive due to the complexity of the surgery. Even with a successful procedure and consistent use of anti-rejection medications, lung transplantation patients have a five-year survival rate on average. Due to these limitations, and constraints from limited donor supply, LVRS and lung transplantation combined have fewer than 2,000 procedures performed for COPD each year in the United States.

In addition to recently approved endobronchial valves, there are other approaches to a minimally invasive alternatives to LVRS, including the use of airway bypass, coils and vapor. However, to date, only endobronchial valves have demonstrated safety and effectiveness in FDA-approved investigational device exemption (IDE) studies in the United States.

### Our Solution

Our solution, which is comprised of the Zephyr Valve, Chartis System and StratX Platform, is designed to treat severe emphysema patients who, despite medical management, are still profoundly symptomatic and either do not want or are ineligible for surgical approaches. Our solution is designed to address the need for a more effective, minimally invasive treatment option for patients with severe emphysema, offering bronchoscopic lung volume reduction without surgery and its associated risks.

Zephyr Valves are indicated for bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. During the one-time bronchoscopic procedure, Zephyr Valves are placed in the airways to occlude the most diseased parts of the lung, allowing trapped air to escape until the lobe is reduced in size. The intended result is a reduction in lung volume and hyperinflation in the targeted area, allowing healthier parts of the lung to expand and take in more air. Patients who are successfully treated with the Zephyr Valve report improved breathing and the ability to go back to doing everyday tasks more easily. When combined with the Chartis System for informed patient selection and treatment planning, Zephyr Valves have been shown to have successful procedure rates of 84-90% in clinical trials.



We believe our solution provides the following important benefits:

- **Significant, durable improvements in lung function, exercise capacity and quality of life**, demonstrated in a substantial body of clinical data;
- **Well-characterized safety profile**, evidenced by the inclusion in global treatment recommendations and over 19,000 patients treated globally with Zephyr Valve;
- **High procedural success** driven by innovative and effective patient assessment tools; and

- **Minimally invasive procedure** typically lasting less than an hour.

In addition, we believe our solution provides several benefits to other key stakeholders:

- For hospitals, the Zephyr Valve represents a new service line with potential economic benefits, driving additional patients to their facilities. Patients who are evaluated require a comprehensive workup that may unveil other health conditions such as heart disease or cancer, which also may require treatment.
- For physicians, the Zephyr Valve enables treatment for a patient population with few alternatives, and the combination of using the StratX Platform and Chartis System are designed to enable a simple, predictable and efficient patient selection process.
- For payors, treatment with the Zephyr Valve has been demonstrated to result in fewer complications and quicker recovery than invasive surgical alternatives and may reduce hospital stays for COPD and incidence of respiratory failure. We believe the combination of using the StratX Platform and Chartis System enables selection and treatment of patients most likely to benefit from our solution.

## **Treatment with Zephyr Valves**

### ***Patient Selection and Treatment Planning***

Patients with advanced COPD routinely undergo a thorough diagnostic workup, which typically includes a high-resolution CT scan of their lungs to determine if they have severe emphysema and hyperinflation. If the patient meets medical eligibility criteria for Zephyr Valves, their CT scan data will be uploaded to our secure cloud-based CT analysis service, the StratX Platform. The treating physician receives an easy-to-read report that we designed for our solution (StratX Lung Report) and based on the report, CT scan and other clinical data, decides if the patient is a good candidate for treatment with Zephyr Valves and which lobes may be the best target for treatment. On the day of the procedure, a flexible camera called a bronchoscope is inserted into the lungs, and using the balloon catheter and console comprising the Chartis System, the physician can determine the presence or absence of collateral ventilation and confirm if the target lobe is likely to respond to treatment. If the assessment shows that there is little to no collateral ventilation to the target lobe (which would refill the lobe with air and limit benefit from the valves), the physician then proceeds to place Zephyr Valves in all airways leading to the target lobe. If there is collateral ventilation in the lobe, the physician may measure another lobe for possible treatment, or decide not to treat the patient with valves.

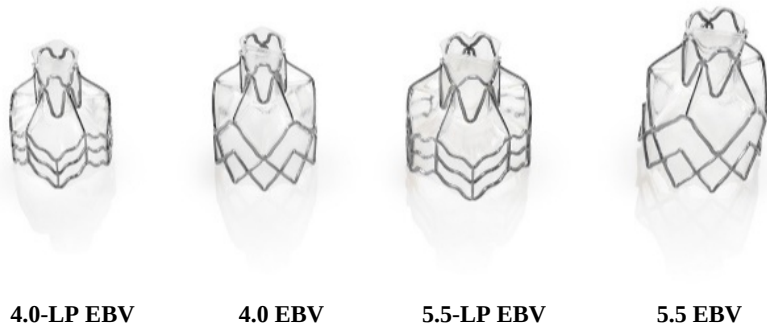
### ***Placement of the Zephyr Valves***

The Zephyr Valve is typically implanted under general anesthesia or conscious sedation. Using our Endobronchial Delivery Catheter (EDC) in a simple, one-step process, physicians select the optimal valve size for each airway. The valves are loaded into the delivery catheter and deployed through the bronchoscope using a controlled release mechanism to enable optimal placement. We offer four valve sizes to accommodate a broad range of airway anatomy that physicians may encounter. Following placement of valves, the patient is kept in the hospital, typically for three nights, to monitor for any side effects including pneumothorax. If a patient develops a pneumothorax, their hospital stay is typically extended by a week.

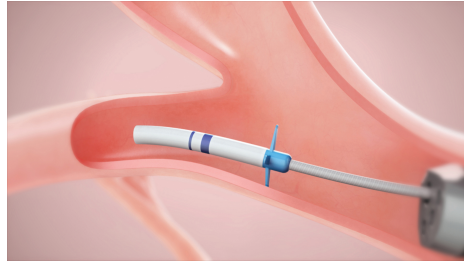
### **Zephyr Valves**

Each of the Zephyr Valves consists of a one-way silicone duckbill valve suspended inside a self-expanding frame made of shape-memory metal, called Nitinol. The Zephyr Valve is designed to be easily and accurately sized and offers controlled and accurate deployment at the target location. The Zephyr Valve is also designed to resist fractures or breakage, adapt to changes in airway size and stay in place following deployment.

The following diagram depicts the four sizes of Zephyr Valves (two different diameters and four lengths).



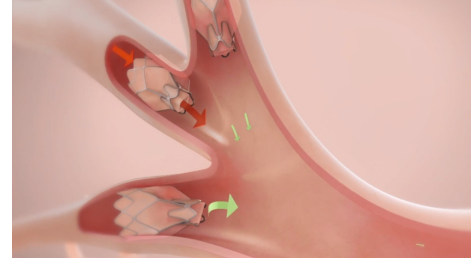
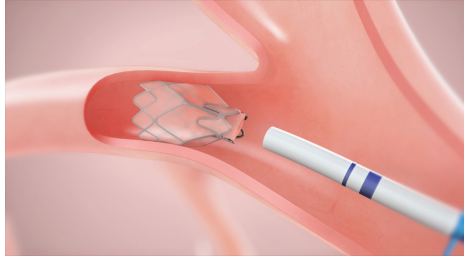
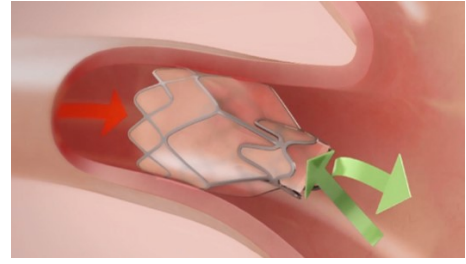
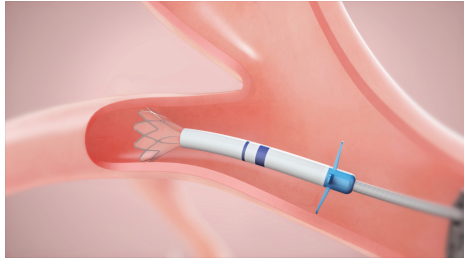
Physicians select the optimal valve size for each airway to be treated using an EDC that includes sizing wings and depth markers, which allows the physician to perform quick and accurate sizing.



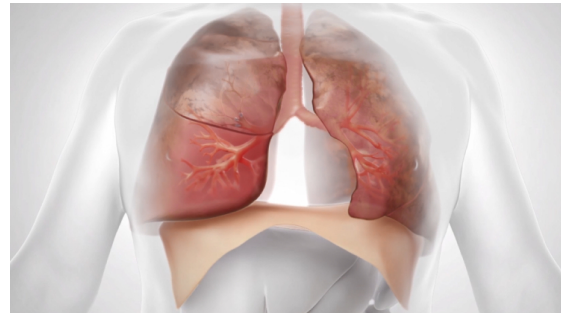
The Zephyr Valve is then loaded into the EDC.



Zephyr Valves offer a controlled, stepwise deployment for easy and accurate placement in the target airway. Once deployed, the valve is held in place by the radial expansion force of the housing. Typically, multiple valves are used to obstruct all airways leading to the target lobe; in clinical studies, an average of four valves per patient were used.



Once the lobe is fully obstructed, air vents out of the treated lobe and is unable to re-enter, causing a reduction in hyperinflation. The treated lobe shrinks in volume over time, allowing the remaining portions of the lung to expand and to restore diaphragm position, making breathing easier.



The Zephyr Valve is designed to be a permanent implant, but unlike surgery, the procedure can be reversed if necessary.

The most common serious complications of treatment with Zephyr Valves can include pneumothorax, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea, respiratory failure and, in rare cases, death. See “Clinical Trials and Results” for a discussion of complications related to Zephyr Valve, including pneumothoraces and death.



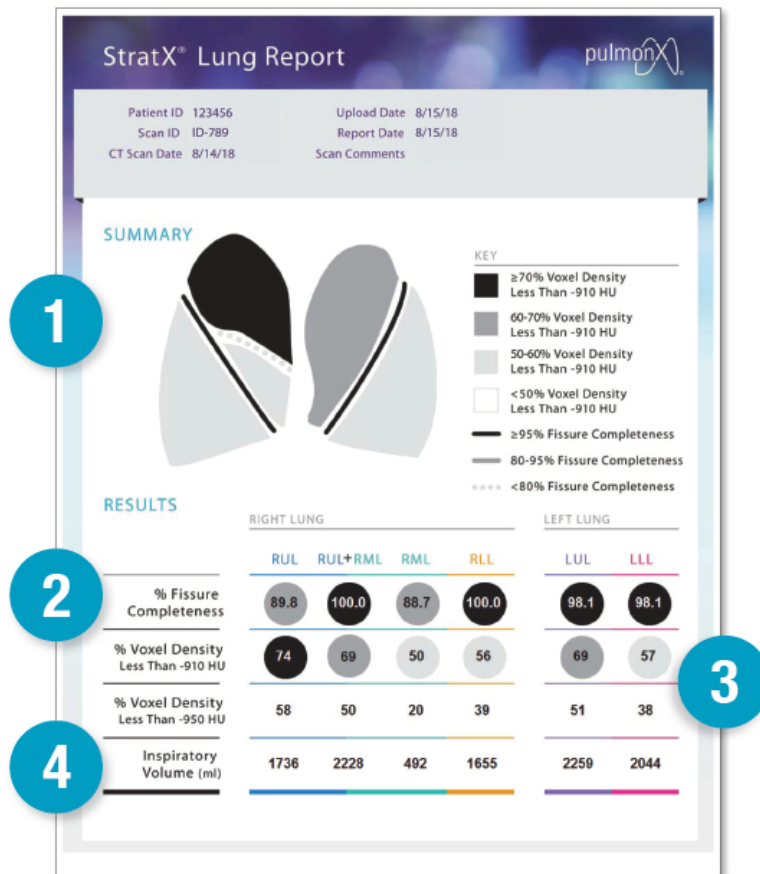
## StratX Platform

The StratX Platform is a cloud-based quantitative CT analysis service that provides physicians with an easy-to-read report that we designed for our solution (StratX Lung Report) that includes information on emphysema destruction, fissure completeness and lobar volume to help identify target lobes for treatment with Zephyr Valves. The StratX Platform is designed to enable physicians to:

- Screen treatment candidates non-invasively;
- Prioritize between multiple potential treatment targets, if applicable;
- Enhance case planning and optimize procedure time; and
- Educate themselves and their patients using the simple to read StratX Lung Report.

In order to make the StratX Platform available to physicians, we contract with a third-party cloud service provider. This third-party cloud service enables physicians to upload CT scan data while removing protected health information (PHI) of patients from that data, in case the physicians have, inadvertently, not removed the PHI themselves. We also contract with additional third-party service providers to analyze the CT scan data using their proprietary software, and provide quantitative results via the StratX Lung Report. The StratX Lung Report is then made available to physicians in the third-party cloud service. The software of each of these third-party service providers has received either 510(k) approval or a CE mark. We provide exclusive access to physicians to their StratX accounts and cases and monitor this CT scan upload and analysis process to ensure quality control.

A sample StratX Lung Report is below, with each section briefly described afterwards.



- Summary Graphic:** The goal of the Zephyr Valve treatment is to completely obstruct and reduce the volume of a target lobe, thereby reducing hyperinflation and improving breathing. In selecting a target lobe, physicians are instructed to look for higher levels of emphysema destruction and presence of complete or nearly complete fissures with neighboring lobes (which has been associated with absence of collateral ventilation and likely response to therapy). The StratX Lung Report contains tabulated data on fissure completeness by lobe, destruction score by lobe and lobar volume. An infographic “key” for easy interpretation of the data is also included. This infographic includes color coding representing the level of emphysema destruction (with darker colors representing lobes with more destruction) and different levels of fissure completeness relative to a target lobe (with darker and more complete lines having greater completeness).
- Fissure Completeness:** Fissure completeness has been shown to be a predictor of success and a surrogate for collateral ventilation between the target and the neighboring lobes. The StratX Lung Report displays fissure completeness values “by lobe,” meaning the values are computed as a percentage of the total area of the fissure across the lobar boundary. The value of fissure completeness between each lobar region is represented with a dark solid, light solid or dotted line. The dark solid line represents fissures that are ≥95% intact. The light solid line represents fissures that are 80-95% intact. The dotted line represents fissures that are <80% intact. A fissure completeness score of <80% indicates the likely presence of collateral ventilation in that lobe, indicating that the lobe should not be considered for treatment with Zephyr Valves.

For fissure completeness values of >80%, fissure completeness should be confirmed using the Chartis System to confirm lobe eligibility.

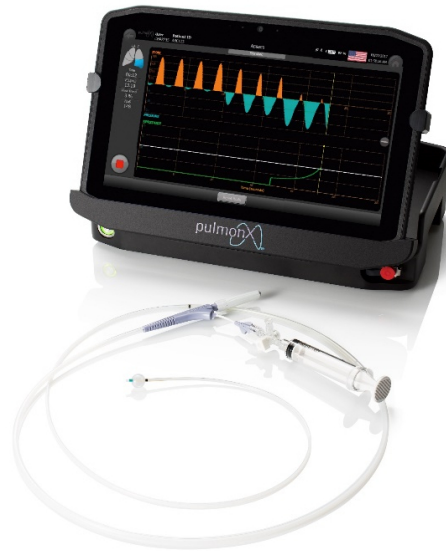
3. **Emphysema Destruction Scoring:** Lobar destruction values of greater than 50% at -910 Hounsfield Units (a measure of tissue density) have been commonly used as an inclusion criterion for various clinical trials of Zephyr Valve treatment. The StratX Lung Report also includes lobar destruction values using -950 Hounsfield Units. In the report and summary view, the degree of shading of a lobe and the numbers within the lobe represent the level of destruction. Lobes with less than 50% destruction are colored white and are usually not considered as potential targets for Zephyr Valve treatment.
4. **Inspiratory Volume:** The inspiratory volume represents the volume of each lobe in mL. The inspiratory volume can help to identify the lobes with the largest volume representing hyperinflation and ones that may be a good target for Zephyr Valve treatment.

To use the StratX Platform, users must have an account set up with us. After the physician captures a CT scan of the patient's chest according to the StratX parameters, the CT scan is de-identified of patient information and the hospital staff uploads the CT scan to our secure encrypted server where it is analyzed using validated algorithms within the StratX Platform. The StratX Platform generates a report that is checked by a trained technician for accuracy and completeness and uploaded to the hospital's account within two to three working days, where it can be downloaded and reviewed by the treating physician.

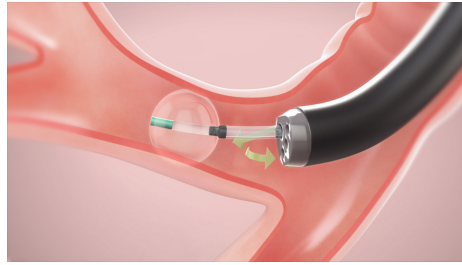
We continue to gather scan data and refine our algorithms in the StratX Platform. We believe that our high volume of reports and data are a source of durable competitive advantage.

### Chartis Pulmonary Assessment System

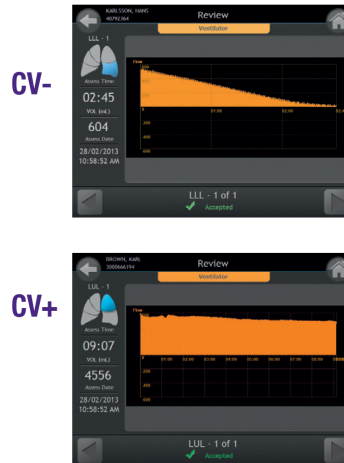
The Chartis System is a proprietary balloon catheter and console system with flow and pressure sensors designed to assess the presence of collateral ventilation and to accurately predict responders to Zephyr Valve treatment. The Chartis System consists of a single-patient-use catheter with a central lumen and a balloon at its tip and a console to allow for the assessment of airflow in the targeted lobe.



When the balloon is inflated, the target lobe is blocked, and air can only escape through the catheter's central lumen.



Airflow and pressure are displayed on the console of the Chartis System allowing for a measurement of collateral ventilation in the targeted lobe. The system works with spontaneous breathing or mechanical ventilation. If the flow of air leaving the occluded lobe is trending towards zero, there is likely no collateral ventilation in the target lobe and it can be successfully treated with Zephyr Valves. By contrast, if the measurement shows continuous airflow from the lobe, the lobe is being refilled through collateral air channels and will likely not respond to Zephyr Valve treatment.



The Chartis System has been validated in multiple randomized controlled clinical trials to predict likely responders to the Zephyr Valve treatment.

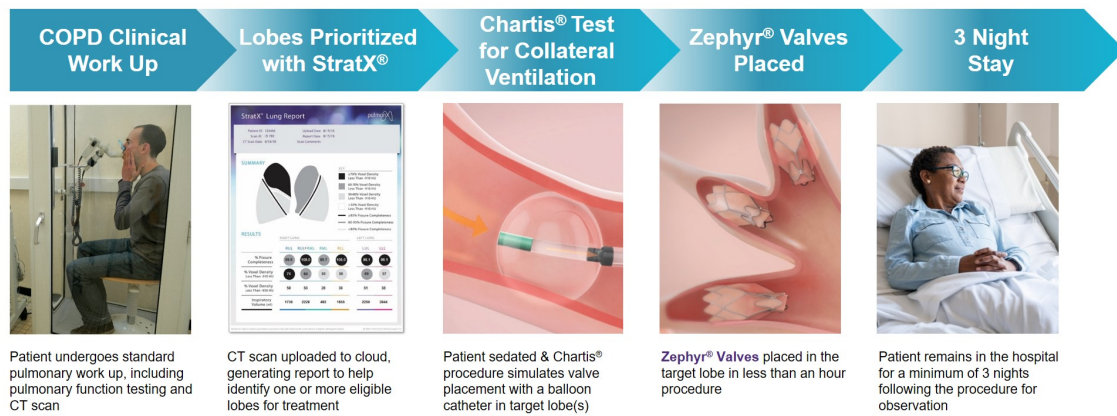
The Chartis System offers a physiologic technique for measuring collateral ventilation and complements non-invasive estimates of fissure completeness. Other methods, such as using fissure analysis as a proxy measurement of collateral ventilation allows detection of an incomplete boundary between the lobes but does not measure how much air is flowing across this gap. This limitation may result in physicians inappropriately screening out many patients who could benefit from valve placement or screening in patients who will likely not respond to valve treatment.

For example, in one early study not sponsored by us that treated patients with a broad range of fissure completeness, approximately 60% of patients who had fissure completeness of 80-90% in the treated lobe had a successful procedure. If a physician was using only quantitative computed tomography (QCT) and a 90% fissure completeness cutoff to select patients, the physician would inappropriately screen out patients in the 80-90% completeness range that could benefit from valve treatment. In that same study, only 72% of patients with a fissure completeness of 90-100% had successful volume reduction in the target lobe. By comparison, patients selected using the Chartis

System in four randomized controlled clinical trials had a success rate of 84%, 88%, 89% and 90%. Thus, while quantitative fissure analysis is an important tool for non-invasively screening out ineligible lobes, we believe it is insufficient for identifying responders to treatment with high accuracy.

## Treatment Steps

The following graphic illustrates the typical treatment steps associated with our solution.



## Pulmonx Market Opportunity

According to the National Center for Health Statistics, as of 2018, 3.8 million people in the United States have been diagnosed with emphysema and we estimate a 10% incidence rate per year; of these, 1.5 million suffer from severe emphysema and 1.2 million also have associated hyperinflation. An estimated 20% of these patients are too sick to undergo a procedure and approximately 50% have collateral ventilation in the lobe targeted for treatment and therefore are not eligible. Of these 1.5 million severe emphysema patients, we estimate that approximately 500,000 patients would qualify for treatment with our Zephyr Valves in the United States, and an additional number may be able to be treated in the future with other technologies under development by us if successfully developed and approved. We also estimate there are approximately 700,000 Zephyr Valve-eligible patients in select international markets. We estimate this represents a global market opportunity of approximately \$12 billion.

## Clinical Trials and Results

The safety, effectiveness and clinical benefits of the Zephyr Valve in patients selected using the Chartis System have been evaluated in multiple randomized controlled clinical trials that have collectively evaluated approximately 450 patients in Austria, Belgium, Brazil, France, Germany, the Netherlands, Sweden, the United Kingdom and the United States. The results of our LIBERATE study, which served as the basis for the FDA approval of our PMA application, were published in the *American Journal of Respiratory and Critical Care Medicine* in 2018 and met all its primary and secondary effectiveness endpoints. In addition, over 100 scientific articles have been published on the clinical benefits of Zephyr Valves, including multiple meta-analyses, review articles, cost-effectiveness analyses and risk-benefit analyses.

Four randomized controlled clinical trials using the Chartis System to select eligible patients (with little to no collateral ventilation) have been completed comparing the treatment of severe emphysema patients with Zephyr Valves with medical management versus medical management alone (which may include drug therapy, pulmonary rehabilitation and supplemental oxygen). All four studies demonstrated statistically and clinically significant benefits across a broad range of endpoints, including measures of lung function, exercise capacity, and quality of life. Patients who received the Zephyr Valve treatment together with medical management experienced increased lung

function, a better quality of life and increased exercise capacity—they could walk farther, could do more daily life activities, such as walking, gardening, and getting ready in the morning, with less shortness of breath. This was due in part to the high rate of procedural success in deflating the target lobe of the lung, ranging from 84-90% in the studies. When the target lobe was properly occluded and isolated from airflow, trapped air in that lobe escaped only through the Zephyr Valves until the lobe volume was reduced. The remaining lobes were then able to expand more fully and work more efficiently, improving overall lung function. Additionally, studies have evaluated the impact of Zephyr Valves on the BODE Index, showing magnitudes of improvement that have been associated with survival benefits.

We are following patients enrolled in the LIBERATE study for up to five years for safety and effectiveness (FEV<sub>1</sub>) assessments. We have also established a patient registry to collect additional data on the safety and effectiveness of the Zephyr Valve (FEV<sub>1</sub>) in the United States. We plan to establish similar registries in France and Belgium in the near future.

### Summary of Key Clinical Results

As seen in table below, the results from multiple randomized clinical trials have consistently shown statistically significant and clinically meaningful benefits of Zephyr Valves across multiple measures of effectiveness.

Randomized Controlled Clinical Trials	Size and Follow-up Period	Procedural Success (TLVR %)	Improvement in:		
			Lung Function (FEV <sub>1</sub> %) ‡ MCID = 10%-15%	Exercise Capacity (6MWD) † MCID = 26 m	Quality of Life (SGRQ) † MCID = -4 pts
<b>LIBERATE</b>	n = 190 12 Mo	84%	18.0% p<0.001	39 m p=0.002	-7.1 pts p=0.004
<b>TRANSFORM</b>	n = 97 6 Mo	90%	29.3 % p<0.001	79 m p<0.001	-6.5 pts p=0.031
<b>IMPACT</b>	n = 93 6 Mo	89%	16.3 % p<0.001**	28 m p=0.016**	-7.5 pts p<0.001**
<b>STELVIO</b>	n = 68 6 Mo	88%	17.8 % P=0.001	74 m p<0.001	-14.7 pts* P<0.001

† Difference between Zephyr Valve and control groups

\* Per protocol, all other values listed are intention to treat (ITT)

\*\* Data included in FDA-approved instructions for use (IFU)

The complications of treatment with Zephyr Valves can include but are not limited to pneumothorax, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea and, in rare cases, death. The most common side effect of Zephyr Valve placement is a pneumothorax, which is the collapse of a lung due to an air leak inside the lung. Pneumothoraces are believed to be a direct result of rapid shifts in air volume in the chest as the target lobe deflates and the neighboring lobe expands. A pneumothorax typically requires placement of a chest tube to manage the air leak. While most pneumothoraces can be readily managed with standard medical care, in rare cases they can be life-threatening, particularly if left untreated. In the event the pneumothorax does not resolve with standard management, one or more valves can be removed to re-inflate the lung; these are typically replaced later when the pneumothorax has resolved. In clinical trials, pneumothoraces occurred in 18-34% of patients treated with the Zephyr Valve, and in the LIBERATE Study, 17% of the pneumothorax events required no intervention and resolved on their own. Patients who have had their pneumothoraces successfully treated had comparable outcomes to those who did not experience a pneumothorax, other than that their hospital stays were extended by approximately a week compared to the three nights for patients without pneumothoraces.

Further, our current products are contraindicated, and therefore should not be used, in certain patients, including patients (i) for whom bronchoscopic procedures are contraindicated, (ii) with evidence of active pulmonary

infection, (iii) with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium) or silicone, (iv) who have not quit smoking or (v) with large bullae encompassing greater than 30% of either lung.

#### *Summary of the LIBERATE Study (Pivotal IDE Study)*

LIBERATE, our pivotal study, was a multicenter, multinational, randomized controlled trial of Zephyr Valves in patients with heterogeneous emphysema and little to no collateral ventilation. The study was conducted between October 2013 and September 2017, and the results were published in May 2018 in the *American Journal of Respiratory and Critical Care Medicine*.

Key inclusion criteria were emphysema patients with heterogeneous disease ( $\geq 15$  difference in destruction scores between the target and adjacent lobes), ex-smokers between 40 and 75 years of age, with post-bronchodilator (BD) forced expiratory volume in one second (FEV<sub>1</sub>) between 15% and 45% predicted, Total Lung Capacity (TLC) greater than 100% predicted, residual volume (RV) equal to or greater than 175% predicted, diffuse capacity of the lung for carbon monoxide equal to or greater than 20% predicted, a Six-Minute Walk Distance (6MWD) between 100 and 500 meters after a supervised pulmonary rehabilitation program and little to no collateral ventilation. Patients with two or more COPD exacerbations requiring hospitalization in the last year, two or more instances of pneumonia in the last year, uncontrolled pulmonary hypertension, myocardial infarction or congestive heart failure in prior six months, and prior lung transplantation, LVRS, bullectomy or lobectomy were excluded from the study.

The Chartis System was used to confirm that all 190 patients had little to no collateral ventilation and would be likely responders to the Zephyr Valve treatment, and were evaluated initially at six months with follow-up for an additional six months.

One hundred ninety patients with hyperinflation were randomized two-to-one for Zephyr Valves plus medical management (Zephyr Valve Group) or medical management alone (which may include drug therapy, pulmonary rehabilitation and supplemental oxygen) (Control Group) (128 Zephyr Valves patients: 62 Control Group patients) and followed for 12 months. Patients in the Zephyr Valve Group had Zephyr Valves placed in the target lobe to achieve lobar occlusion. Both the Zephyr Valve Group and Control Group patients continued to receive optimal medical management according to current clinical practice. Following their 12-month evaluation, the Control Group patients had an option to receive Zephyr Valve treatment, of which 47 out of 59 (80%) elected to do so. The LIBERATE study had high patient retention with 94% of patients completing follow-up for evaluation for 12 months.

The primary effectiveness endpoint was the percentage of patients enrolled in the Zephyr Valve Group who met the threshold of  $\geq 15\%$  improved FEV<sub>1</sub> as compared to the Control Group at 12 months.

The secondary effectiveness endpoints included standard validated assessments commonly used in COPD studies:

- 1) FEV<sub>1</sub>, a measure of lung function: Difference between the Zephyr Valve Group and the Control Group in absolute change from baseline for FEV<sub>1</sub> at 12 months;
- 2) 6MWD, a measure of exercise capacity: Difference between the Zephyr Valve Group and Control Group in absolute change from baseline for 6MWD at 12 months; and
- 3) St. George's Respiratory Questionnaire (SGRQ), a measure of quality of life: Difference between the Zephyr Valve Group and Control Group in absolute change from baseline for SGRQ score at 12 months.

Other endpoints included additional measures of lung function, exercise capacity, breathlessness and quality of life. Adverse events and serious adverse events were evaluated for the Treatment Period (day of procedure to 45 days), and Long-Term Period (46 days after procedure to 12 months) to assess safety.

## Results

### Effectiveness

The study met its primary and secondary endpoints at 12 months.

In the Zephyr Valve Group, 47.7% of patients achieved an FEV<sub>1</sub> improvement of  $\geq 15\%$  from baseline to 12 months compared to 16.8% of patients in the Control Group ( $p < 0.001$ ).

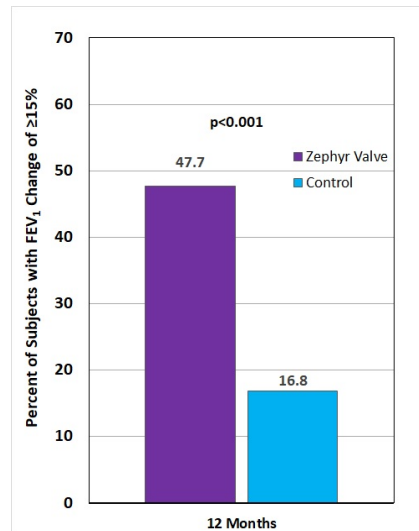


Figure shows the primary endpoint of FEV<sub>1</sub> Responders (FEV<sub>1</sub> improvement of  $\geq 15\%$ ) at 12 months

The absolute change in FEV<sub>1</sub> showed significantly greater mean improvement (improved forced expiratory volume) in the Zephyr Valve Group compared to the Control Group ( $\Delta$  Zephyr Valve - Control = +0.106L,  $p < 0.001$ ); the 6MWD showed significantly greater mean improvement (increased distance walked) in the Zephyr Valve Group compared to the Control Group ( $\Delta$  Zephyr Valve - Control = +39.31 meters,  $p = 0.002$ ), and the SGRQ showed significantly greater mean improvement (score reduction) in the Zephyr Valve Group compared to the Control Group ( $\Delta$  Zephyr Valve - Control = -7.05,  $p = 0.004$ ).

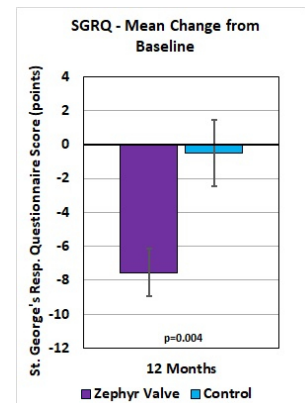
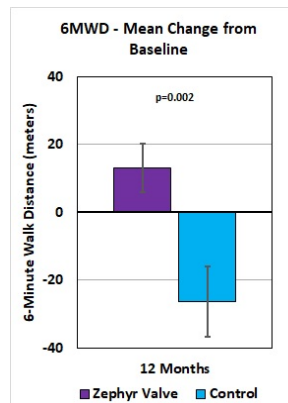
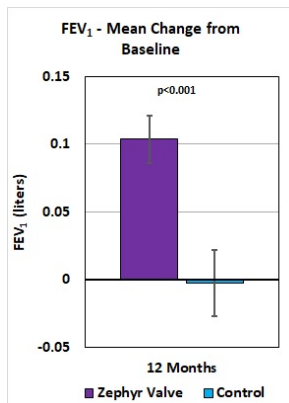


Figure above presents secondary endpoints as mean changes  $\pm$  standard error of the mean (SEM) from baseline to 12 months for the Zephyr Valve and Control Groups



Target lobe volume reduction was successfully achieved with 84% of patients having volume reductions of 350 mL or greater, where 350 mL lobe volume reduction is considered to be the Minimal Clinically Important Difference (MCID). Across a broad range of effectiveness endpoints, patients in the Zephyr Valve Group showed a substantially higher rate of clinically meaningful benefits when compared to patients in the Control Group, with responder rates ranging from 42-62% for individual measures.

73% of patients in the Zephyr Valve Group had a clinically meaningful response to at least one of FEV<sub>1</sub>, 6MWD and SGRQ score. Responder rates based on the individual MCID for the various endpoints at 12 months are shown in the figure below.

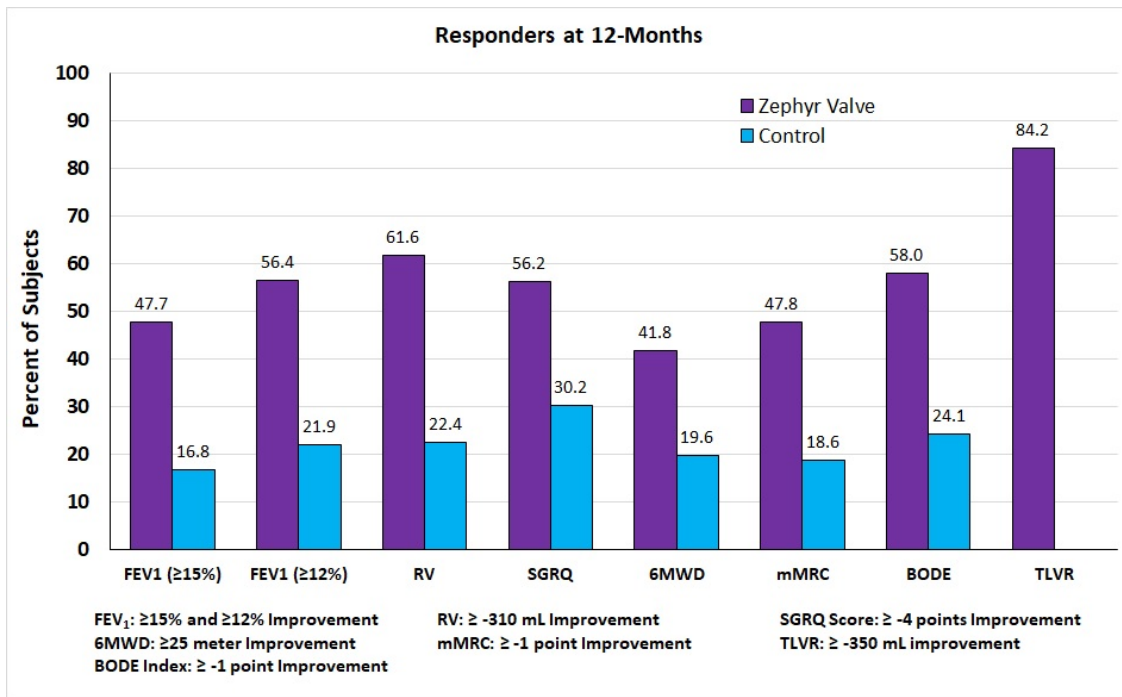


Figure above shows Responder rates based on individual MCID for various endpoints at 12 months

The safety of the treatment with Zephyr Valves was assessed by comparing adverse event profiles of patients in the Zephyr Valve Group and Control Group occurring over two time periods: Treatment Period (day of procedure to 45 days) and the Longer-Term Period (46 days after procedure to 12 months). Serious adverse events included pneumothorax, COPD exacerbation, pneumonia, respiratory failure and death.

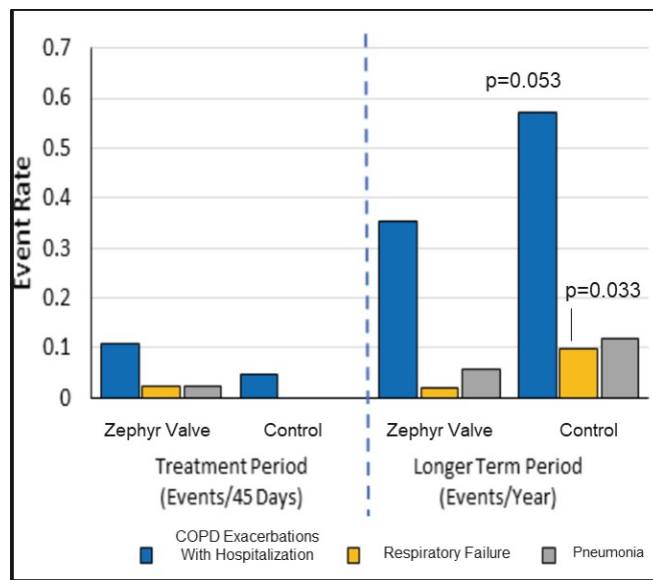
	Proportion of Patients Experiencing Pulmonary Serious Adverse Events Occurring in at Least 3% of Patients in Zephyr Valve and Control Groups					
	Treatment Period 0 to 45 days			Longer-Term Period 46 days to 12 months		
	Zephyr Valve Group N=128	Control Group N=62	$\Delta$ Zephyr Valve - Control	Zephyr Valve N=128	Control N=62	$\Delta$ Zephyr Valve - Control
Death	3.1%	0%	3.1%	0.8%	1.6%	-0.8%
Pneumothorax	26.6%	0%	26.6%	6.6%	0%	6.6%
COPD Exacerbation	7.8%	4.8%	3.0%	23.0%	30.6%	-7.6%
Pneumonia	0.8%	0%	0.8%	5.7%	8.1%	-2.4%
Respiratory Failure	1.6%	0%	1.6%	0.8%	3.2%	-2.4%

There were a higher number of serious adverse events in the Zephyr Valve Group compared to the Control Group during the Treatment Period. The most common serious adverse events in the Zephyr Valve Group versus the Control Group during the Treatment Period were pneumothorax and COPD exacerbations.

The majority of pneumothoraces (76%) occurred within three days following a bronchoscopy procedure. Four deaths occurred in the Treatment Period in the Zephyr Valve Group and none in the Control Group. Three of the four deaths were deemed by the investigators to be definitely related to treatment with Zephyr Valves and the remaining one was deemed by the investigators to be probably related to treatment with Zephyr Valves. Each patient that died experienced pneumothorax, with three deaths directly attributed to the pneumothorax and the fourth death the result of respiratory failure after the pneumothorax had resolved. In order to more closely monitor patients, the study protocol was subsequently amended to keep patients in the hospital for five nights. Based on the full study data, current practice is to keep patients in hospital for a minimum of three nights post-treatment. Post-hoc analysis has helped us identify risk factors for the group of patients at higher risk of having a complex pneumothorax event (complex pneumothorax defined as requiring removal of all valves or resulting in death) should one occur. Such high-risk patients include those who are not treated in the most diseased lobe and have greater than 60% destruction of the untreated lung. All four patients who experienced a pneumothorax and died were within this high-risk group. Further, all four pneumothorax events occurred in subjects that were not treated in the most diseased lobe and had more than 60% emphysema destruction in the contralateral lung. This learning is incorporated in our physician training program for physicians to identify such high-risk patients and to consider alternative targets or other risk mitigation strategies. During the Longer-Term Period, there was one death (0.8%) in the Zephyr Valve Group from a COPD exacerbation, deemed by the investigators not to be related to treatment with Zephyr Valves, and one cardiac arrhythmia death in the Control Group (1.6%).

Patients who experienced a pneumothorax following treatment with Zephyr Valves and whose pneumothorax had been resolved, experienced meaningful clinical benefit once they recovered from the pneumothorax event, with benefits comparable to patients who did not experience such pneumothorax events.

In the Longer-Term Period, the Zephyr Valve Group showed a non-statistically meaningful trend towards a reduction in COPD exacerbations requiring hospitalization and statistically significant reductions in respiratory failure events.



There were a number of secondary bronchoscopy procedures (consistent with study protocol) either to adjust a valve or to manage adverse events. There were 11 adjustment procedures in 11 patients following verification of lobar occlusion from the HRCT-assessment at 45-days. There were 21 procedures purely for valve removal (related to an adverse event) in 17 patients, and ten valve replacement procedures in eight patients (valve replacement procedures could entail simultaneous removal and replacement, or replacement for a valve previously removed). Five patients experienced a pneumothorax event following a valve adjustment procedure. See also “Risk Factors — Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations.”

#### Summary of the TRANSFORM Study

The TRANSFORM study was a company-sponsored, multicenter, prospective, randomized, controlled clinical trial of Zephyr Valve treatment in patients with heterogeneous severe emphysema and little to no collateral ventilation conducted at 17 study sites in Europe. The study was conducted between January 2014 and April 2017, and the results were published in September 2017 in the *American Journal of Respiratory and Critical Care Medicine*.

Key inclusion criteria were severe emphysema patients with heterogeneous disease ( $\geq 10$  difference in destruction scores between the target and adjacent lobes), ex-smokers over 40 years of age, with post-BD FEV<sub>1</sub> between 15% and 45% predicted, TLC greater than 100% predicted, RV equal to or greater than 180% predicted, and a 6MWD between 100 and 450 meters and little to no collateral ventilation. Patients with two or more COPD exacerbations requiring hospitalization in the last year, known pulmonary hypertension, myocardial infarction or other cardiovascular events in prior six months, and prior lung transplantation, LVRS, bullectomy or lobectomy were excluded from the study. Eligible patients were randomly assigned at a 2:1 ratio into either the Zephyr Valve treatment plus medical management (Zephyr Valve Group) or medical management alone (which may include drug therapy, pulmonary rehabilitation and supplemental oxygen) (Control Group) (65 Zephyr Valve patients: 32 Control Group patients).

The Chartis System was used to confirm that all 97 patients had little to no collateral ventilation and would be likely responders to the Zephyr Valve treatment, and were evaluated initially at six months with follow-up for an additional six months.

Patients in both groups were observed at 45-day, three-month and six-month periods. Patients in the Control Group were required to complete a minimum six-month follow-up. Following their six-month evaluation, the Control Group patients had an option to receive Zephyr Valve treatment, if eligible, which is commercially available in Europe, or remain in the Control Group for an additional six months. Only two Control Group patients elected to continue for an additional six months and the other patients opted to seek Zephyr Valve treatment commercially.

The primary effectiveness endpoint was the percentage of patients in the Zephyr Valve Group meeting the MCID of  $\geq 12\%$  improved post- BD FEV<sub>1</sub> at three months post-treatment compared to the percentage of patients in the Control Group.

Other endpoints included additional measures of lung function, exercise capacity, breathlessness, hyperinflation, health status and quality of life measures. Adverse events and serious adverse events were evaluated for the Treatment Period (day of procedure to 45 days) and Longer-Term Period (46 days from procedure day to six months).

## Results

### Effectiveness

The study met its primary and secondary endpoints at three months.

At three months, 55% of patients on an ITT basis and 67% of patients on a per protocol (PP) basis achieved a  $\geq 12\%$  change in FEV<sub>1</sub> from baseline, compared to 6.5% for the ITT and 6.7% for the PP patients in the Control Group ( $p < 0.001$  for both). This was statistically superior to medical management alone.

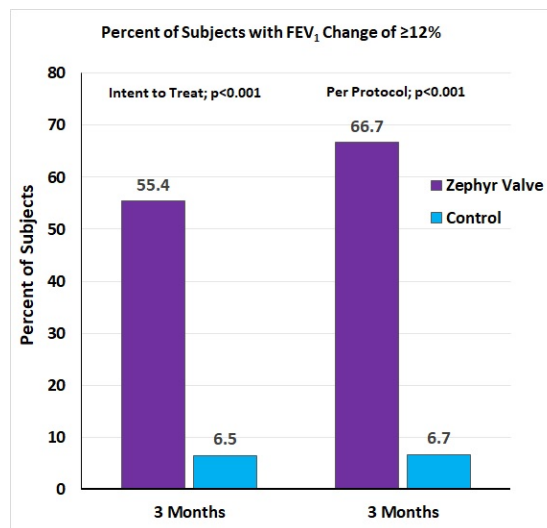
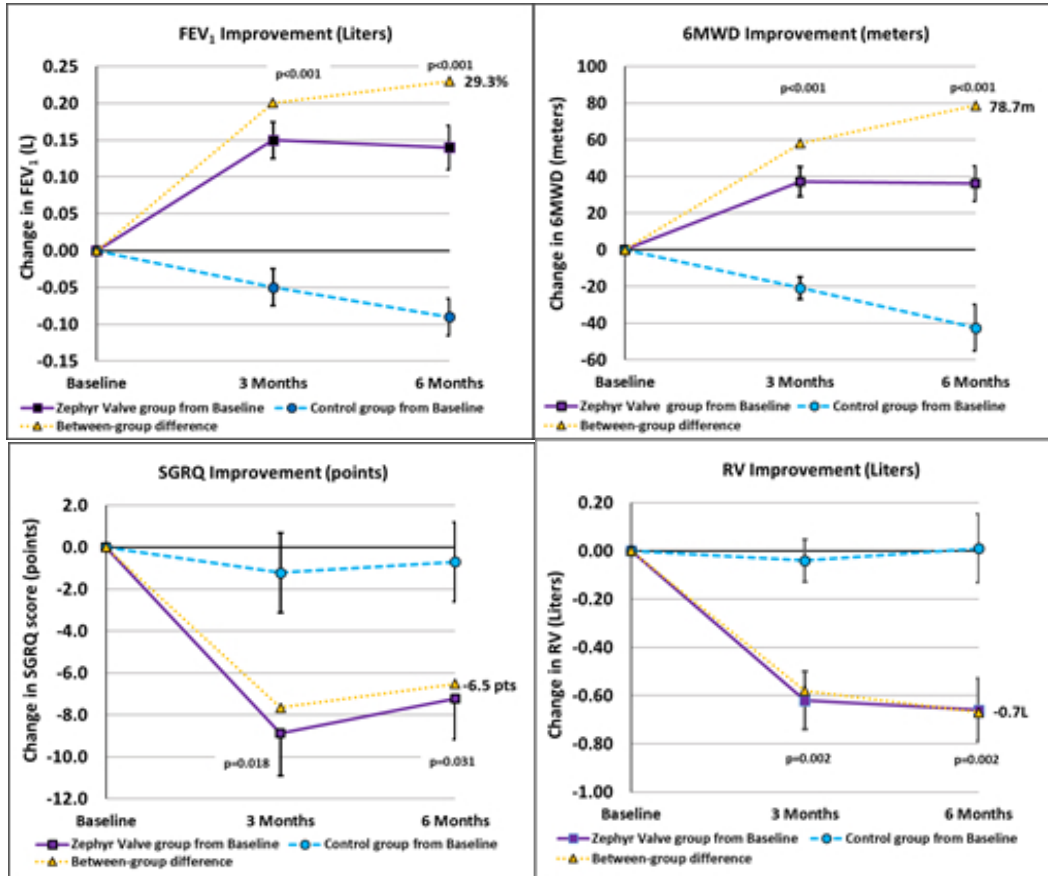
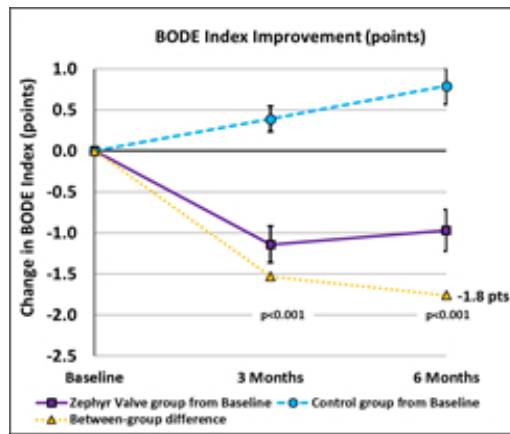


Figure above shows the responder rate (primary endpoint) for the Intention-to-Treat and Per Protocol Populations at three months

The study met its secondary endpoints, with durable and statistically significant benefits in favor of the Zephyr Valve Group out to six months across multiple measures. Lung function assessed by FEV<sub>1</sub> showed a 29% (p<0.001) improvement in the Zephyr Valve Group over the Control Group, exercise capacity assessed by 6MWD improved by 79 meters (p<0.001), quality of life assessed by the SGRQ score improved by 6.5 points (p=0.031), hyperinflation assessed by a decrease in residual volume improved by 670 mL (p=0.002), and health status assessed by the BODE Index improved by 1.75 points (p<0.001). Target lobe volume reduction was successfully achieved with 90% of patients having volume reductions of greater than MCID.





Figures above show the improvements over time for FEV<sub>1</sub>, 6MWD, SGRQ, RV, and BODE Index out to six months.

### Safety

At six months, 47.7% patients in the Zephyr Valve Group compared to 9.4% patients in the Control Group ( $p < 0.001$ ) had a respiratory related serious adverse event, with most events occurring within 45 days of the procedure. In the Zephyr Valve Group, there were 13 pneumothorax events in 13 patients (20%) during the 45-day Treatment Period ( $p = 0.004$ ). None of the other respiratory serious adverse events were statistically different between groups during the same period. Over the longer term (46 days through six months), there was no difference in respiratory serious adverse events between groups. There was one death in the Zephyr Valve Group due to an in-hospital cardiac arrest as a complication of a pneumothorax and was deemed by the investigator to be related to treatment with Zephyr Valves. See also “Risk Factors — Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations.”

### Summary of the IMPACT Study

The IMPACT Study was a company sponsored, multicenter, randomized, controlled clinical trial of Zephyr Valves in patients with severe homogeneous emphysema at eight investigational sites in Europe. The study was conducted between August 2014 and March 2017, and the results of the primary endpoint at three months were published in August 2016 in the *American Journal of Respiratory and Critical Care Medicine*.

Key inclusion criteria were emphysema patients with homogeneous disease (<15 difference in destruction scores between the target and adjacent lobes), ex-smokers over 40 years of age, with post-BD FEV<sub>1</sub> between 15% and 45% predicted, TLC greater than 100% predicted, RV equal to or greater than 200% predicted, a 6MWD equal to or greater than 150 meters and little to no collateral ventilation. Patients with three or more COPD exacerbations requiring hospitalization in the last year, known pulmonary hypertension, myocardial infarction or other relevant cardiovascular events in prior six months, and prior LVR or LVRS, and greater than 20% difference in perfusion between the left and right lung were excluded from the study. Eligible patients were randomly assigned at a 1:1 ratio into either the Zephyr Valve procedure plus medical management (Zephyr Valve Group) or medical management alone (which may include drug therapy, pulmonary rehabilitation and supplemental oxygen) (Control Group) (43 Zephyr Valve patients: 50 Control Group patients).

The Chartis System was used to confirm that all 93 patients had little to no collateral ventilation and would be likely responders to the Zephyr Valve treatment, and were evaluated initially at six months with follow-up for an additional six months.

The primary effectiveness endpoint was the percentage change in FEV<sub>1</sub> at three months relative to baseline in the Zephyr Valve Group, compared to the Control Group.

Other endpoints included additional measures of lung function, exercise capacity and quality of life measures. Adverse events and serious adverse events were evaluated for the Treatment Period (day of procedure to 30 days), and Long-Term Period (31 days after procedure to six months).

## Results

### Effectiveness

The study met its primary effectiveness endpoint. The mean percent change in FEV<sub>1</sub> (L) from baseline to three months in the Zephyr Valve Group was an increase of 15.3% compared to a decrease of 3.4% in the Control Group. The mean group difference for the change in FEV<sub>1</sub> from baseline to three months was 18.8 ± 22.1% (mean ± SD; p <0.001). Similar changes were observed in the ITT population. The mean percent change in FEV<sub>1</sub> (L) from baseline to three months in the Zephyr Valve Group was an increase of 13.7% compared to a decrease of 3.2% in the Control Group. The mean group difference (Zephyr Valve - Control) for the change in FEV<sub>1</sub> from baseline to three-months was 17.0 ± 21.4% (mean ± SD; p <0.001).

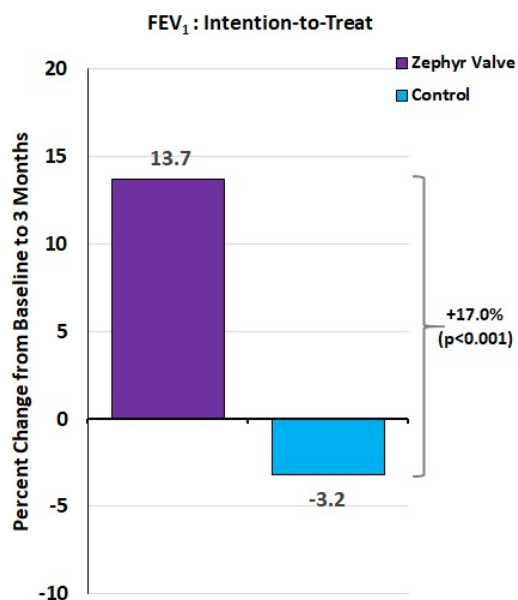


Figure above shows the percent change of FEV<sub>1</sub> from baseline (primary endpoint) for the ITT groups at three months

The study also met its secondary outcomes. There were statistically significant and clinically meaningful improvements from baseline in the Zephyr Valve Group versus the Control Group at three months and six months with differences between the Zephyr Valve Group and Control Group for FEV<sub>1</sub> (120 mL at 3 months and 120 mL at six months; p<0.001), RV (480 mL at three months and 430 mL at six months; p=0.011 and p=0.015, respectively), 6MWD (40 meters at three months and 28 meters at six months; p=0.002 and p=0.0156, respectively), SGRQ score (-9.6 at three months and -7.5 at six months; p<0.001), and Modified Medical Research Council (mMRC) Dyspnea Scale scores (-0.6 at three months and -0.4 at six months; p=0.01 and p=0.048, respectively). Target lobe volume reduction was successfully achieved with 89% of patients having volume reductions of greater than MCID.

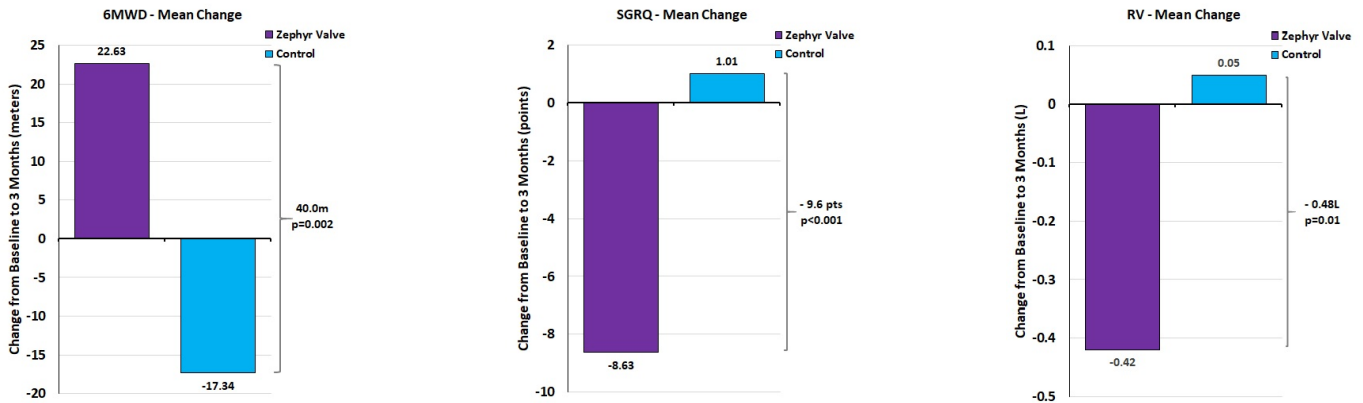


Figure above presents secondary endpoints as mean changes ± SEM from baseline to six months for the Zephyr Valve and Control Groups

### Safety

There were a higher number of respiratory serious adverse events in the Zephyr Valve Group compared to the Control Group during the Treatment Period (day of procedure to 30 days; 44.2% patients versus 2.0% patients). The most common respiratory serious adverse events in the Zephyr Valve Group versus the Control Group during the Treatment Period were pneumothorax in 23.3% versus 0.0%, respectively; and COPD exacerbations in 14.0% versus 2.0% patients, respectively. All pneumothoraces were managed using standard techniques that included chest tube placement and careful observation. There were a comparable number of serious respiratory adverse events in the Zephyr Valve Group compared to the Control Group during the Longer-Term Period (31 days to six months; 34.9% patients versus 26.0% patients, respectively).

The most common respiratory adverse events in the Zephyr Valve Group versus Control Group during the Longer-Term Period were COPD exacerbations in 18.6% versus 20.0% patients, respectively; dyspnea in 4.7% versus 0.0% patients, respectively; pneumothorax in 4.7% versus 0.0% patients, respectively; pneumonia in 2.3% versus 4.0% patients, respectively; and hypercapnia in 0.0% versus 6.0% patients, respectively. There were no deaths in the Zephyr Valve Group and two deaths in the Control Group that occurred in the Longer-Term Period. There was one death in the Zephyr Valve Group that occurred beyond 12-months after the Zephyr Valve implantation following severe COPD exacerbation after an abdominal surgery and was not related to treatment with Zephyr Valves. See also “Risk Factors — Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations.”

### Summary of the STELVIO Study

The STELVIO study was an independent, non-company sponsored, randomized, controlled clinical trial conducted at a single center in the Netherlands that evaluated 68 patients with severe emphysema and hyperinflation. The study



was conducted between June 2011 and November 2014, and the results of the primary endpoint were published in November 2015 in *The New England Journal of Medicine*.

Key inclusion criteria were severe emphysema patients with heterogeneous and homogenous disease, ex-smokers over 35 years of age, with post-BD FEV<sub>1</sub> less than 60% predicted, TLC greater than 100% predicted, RV greater than 150% predicted, dyspnea score of equal to or greater than two on the mMRC Dyspnea Scale, a 6MWD equal to or greater than 140 meters, and little to no collateral ventilation. Key exclusion criteria were prior LVRS, lung transplantation or lobectomy and evidence of other disease that may compromise survival or would interfere with completion of study. Eligible patients were randomly assigned at a 1:1 ratio to either Zephyr Valve treatment plus medical management (Zephyr Valve Group) or medical management alone (which may include drug therapy, pulmonary rehabilitation and supplemental oxygen) (Control Group) (34 Zephyr Valve patients: 34 Control Group patients).

The Chartis System was used to confirm that all 68 patients had little to no collateral ventilation and would be likely responders to the Zephyr Valve treatment, and were evaluated initially at six months with follow-up for an additional six months.

The primary outcome measures included differences between groups for changes in FEV<sub>1</sub>, Forced Vital Capacity (FVC) and 6MWD from baseline to six months.

Secondary outcome measures, among patients who completed the study, were improvements from baseline to six months in FEV<sub>1</sub>, FVC, 6MWD, SGRQ score and other health related measures.

## Results

### Effectiveness

The study met its primary and secondary effectiveness outcomes.

There were significantly greater improvements in the Zephyr Valve Group than in the Control group from baseline to six months with a between group increase in FEV<sub>1</sub> of 140 mL (95% confidence interval (CI), 55 to 225), in FVC of 347 mL (95% CI, 107 to 588), in the 6MWD of 74 m (95% CI, 47 to 100) ( $p < 0.01$  for all comparisons). The data are depicted in the figure and table below. Target lobe volume reduction was successfully achieved with 88% of patients having volume reductions of greater than MCID.

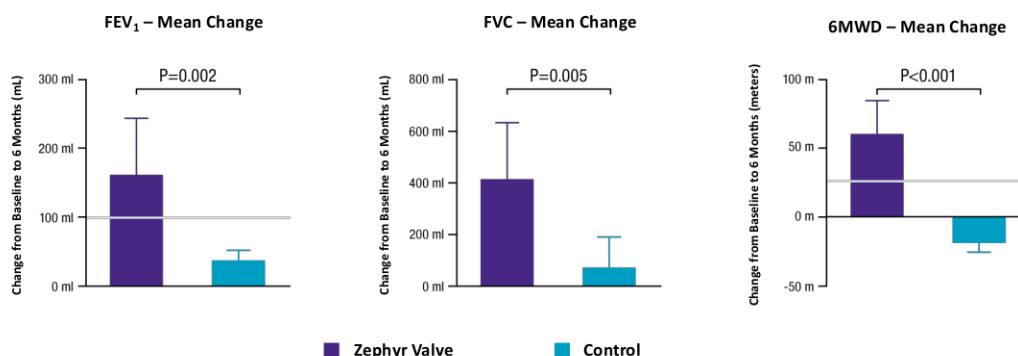


Figure above presents the co-primary endpoints as mean changes with 95% confidence intervals from baseline to six months for the Zephyr Valve and Control Groups

**Effectiveness Outcomes for the Zephyr Valve and Control Groups at Six Months  
Values are Mean Change from Baseline for ITT Population**

	<b>Zephyr Valve Group N=34</b>	<b>Control Group N=34</b>	<b>Difference Between Groups (Zephyr Valve - Control)</b>
FEV <sub>1</sub> (%)	+20.9	+3.1	+17.8
FVC (%)	+18.3	+4.0	+14.4
6MWD (%)	+19.6	-3.6	+23.3

STELVIO was also the first randomized trial that evaluated outcomes in patients with homogeneous disease versus heterogeneous disease and showed that both groups benefited from treatment with Zephyr Valves. In general, the clinical outcomes after Zephyr Valve treatment were lower in the homogeneous patients compared to the heterogeneous patients but were still clinically meaningful (i.e., were greater than the MCID for each measure).

**Effectiveness Outcomes for the Zephyr Valve Group who Completed the Study  
Values are Mean Change from Baseline**

	<b>Homogeneous Emphysema N=29</b>	<b>Heterogeneous Emphysema N=22</b>
FEV <sub>1</sub> (%)	+20.1	+32.6
RV (%)	-16.3	-16.6
6MWD (meters)	+69	+72
SGRQ score (points)	-13	-19

In subsequent follow-up of patients in the STELVIO study, these results were shown to be durable to at least one year. Furthermore, the BODE index at one year showed an improvement from baseline of -1.13 points (95% CI, -1.5 to -0.7; p <0.001); a reduction of more than one point in the BODE Index being associated with a decrease in mortality.

### *Safety*

Over the six months, there were 23 serious adverse events in the Zephyr Valve Group, as compared with five in the Control group (p<0.001). Serious treatment related adverse events in the Zephyr Valve Group included pneumothorax (18% of patients) and events requiring valve replacement (12%) or removal (15%). There was one death in the Zephyr Valve Group due to end-stage COPD with respiratory failure 58 days after treatment which was deemed by the investigator to be unrelated to treatment with Zephyr Valves.

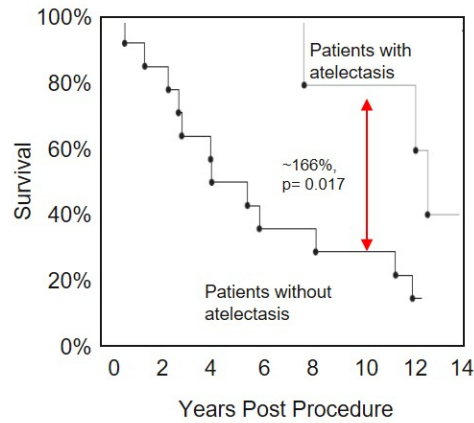
There was one death during the six-month to 12-month period in the Zephyr Valve Group due to a myocardial infarction (313 days after treatment) unrelated to treatment with Zephyr Valves. In the Control Group, there were two deaths recorded at 160 and 267 days after the screening visit, both due to COPD progression. See also “Risk Factors — Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations.”

### *Other Clinical Trials*

The VENT study was a multi-center randomized clinical trial conducted in the mid-2000s by Emphasys Medical evaluating the safety and effectiveness of the Zephyr Valve. The study enrolled 321 patients in the United States. While the study showed statistically significant improvement in FEV<sub>1</sub> and 6MWD (co-primary endpoints), these were only clinically significant in a post hoc subset of patients that had complete fissures (a surrogate for absence of collateral ventilation) and lobar occlusion. The study did not meet its primary endpoints.

The BeLieVeR-HiFi study was a single center randomized, controlled, independent, non-company-sponsored study conducted in the early 2010s that enrolled 50 patients with complete fissures and severe heterogeneous emphysema. Patients were randomized to treatment with Zephyr Valves and medical management or a sham procedure and medical management. While Chartis assessment was performed to assess collateral ventilation prior to the procedure, inclusion in the study was based on visual assessment of complete fissures. The study showed clinical benefit in the Zephyr Valve treated patients although the outcomes were better in patients in whom collateral ventilation was ruled out using the Chartis System.

We are not aware of any prospective data regarding survival rates of patients who have undergone endobronchial valve treatment. There is one retrospective study, however, of 449 patients five years following valve treatment, that suggested that patients with atelectasis (target lobe volume reduction) were approximately 45% more likely to survive than patients without. Another retrospective study of 19 patients ten years following valve treatment suggested that patients with atelectasis were approximately 166% more likely to survive than patients without atelectasis.



### Our Commercial Strategy

We have established a stepwise approach to market development which centers on active engagement across three key stakeholders in addressing severe emphysema: hospitals, physicians and patients.

We sell Zephyr Valves primarily through a direct sales force that engages with pulmonologists in the United States, Europe and Asia Pacific. Zephyr Valves are typically implanted by an interventional pulmonologist at a hospital, and patients are often evaluated in a multi-disciplinary team approach that includes other lung physicians, radiologists, respiratory therapy specialists or surgeons. Our sales personnel work closely with these stakeholders to ensure quality outcomes. We offer an in-depth training program developed in conjunction with leading global thought leaders and the largest pulmonary society in the United States. Our sales personnel work with hospitals to leverage their existing resources to efficiently establish and market Zephyr Valves as a service line. Our sales territory managers also call on community physicians and pulmonary rehabilitation centers to raise awareness of Zephyr Valves as a treatment option.

We currently have 32 sales territory managers in the United States. We also currently have 26 sales territory managers outside of the United States, with 18 in Europe and eight in Asia Pacific. We seek to recruit territory managers with strong sales backgrounds, with direct experience developing markets with new technologies and an understanding of medical device reimbursement and the prior authorization process. In the United States, our territory managers are managed by region directors. We plan to expand our commercial organization, recruiting and

training talented sales territory managers in existing and new markets in the United States to help facilitate further adoption and broaden awareness of Zephyr Valves. 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 solution in order to drive revenue growth.

Our strategy is to identify territories with high unmet need, identify leading hospitals and work with champions of our solution to build emphysema centers of excellence. We believe there is a significant growth opportunity for hospitals to provide high quality comprehensive diagnosis and treatment for advanced COPD patients. We believe we can efficiently serve the United States market, focusing on approximately 500 high volume hospitals, of which we currently cover a small fraction.

We intend to continue to promote awareness of our solution through training and educating physicians, pulmonary rehabilitation centers, key opinion leaders and various medical societies on the proven clinical benefits of Zephyr Valves. We continue to develop our relationships with credible third parties, such as our partnership with the American College of Chest Physicians, on continuing medical education-accredited training and with the COPD Foundation on patient and physician education. We also intend to continue helping physicians in their outreach to patients and other healthcare providers. In addition, we intend to continue to publish additional clinical data in various industry and scientific journals, online and through presentations at various industry conferences. We believe that many patients who suffer from severe emphysema are eager for a minimally invasive option such as the Zephyr Valve. We also plan to continue building patient awareness through our direct-to-patient marketing initiatives, which include advertising, social media and online education. We also intend to continue helping physicians in their outreach to patients and other healthcare providers.

The objective of this outreach is to bring patients to our website, where they can find educational materials on Zephyr Valves, determine if they may be eligible, find contact information for physicians in their area and sign up for support and news.

We believe our patient outreach efforts have been effective in bringing potential patients to our website and facilitating contact with hospitals that provide more information about our solution. In the fourth quarter of 2019, we had over 100,000 visitors to our website; over 2,000 visitors used our website to find a physician or hospital that provides our solution in their area, and we registered more than 1,800 calls to such hospitals to schedule an appointment.

### ***Commercial Activities Outside of the United States***

We conduct our international business through direct sales in markets with established reimbursement and substantial market potential, and through a distributor-based sales model in smaller markets or markets where we are still developing reimbursement. Direct sales represented over 90% of our international sales in 2019, which totaled \$ .

We currently have 26 territory managers in international markets in which we make direct sales, with 18 in Europe and eight in Asia Pacific, including in Australia, Austria, France, Germany, Italy, the Netherlands, Spain, Switzerland and the United Kingdom. We also maintain a direct sales presence in China to support our sub-distributors and distributors.

Our strategy is to offer limited distribution and develop champions of our solution in high potential markets, and as reimbursement becomes available, change from a distributor-based sales model to a direct sales model. We have successfully followed this approach in most markets outside the United States in which we sell and we anticipate following a similar approach in the future.

### **Third-Party Reimbursement**

There are three key components for reimbursement in the United States: (1) coding, (2) payment and (3) coverage. Our patient reimbursement support team is responsible for all aspects of our reimbursement processes and

initiatives. In the United States, our solution is reimbursed based on established Category I CPT and ICD-10 PCS codes and associated MS-DRG and APC payment groupings.

### ***Coding***

In the United States, we sell our products to hospitals. 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 standard codes for both physician and facility payments. “Coding” refers to distinct numeric and alphanumeric billing codes that are used by healthcare providers to report the provision of medical services procedures and the use of supplies for specific patients to payors. CPT codes are published by the American Medical Association and are used to report medical services and procedures performed by or under the direction of physicians. Medicare pays physicians for services based on submission of a claim using one or more specific CPT codes. Physician payment for procedures may vary according to site of service. Hospitals are reimbursed for inpatient procedures based on MS-DRG classifications derived from ICD-10-CM diagnosis and ICD-10 PCS codes that describe the patient’s diagnoses and procedures performed during the hospital stay. MS-DRG classifications closely calibrate payment for groups of services based on the severity of a patient’s illness and clinical cohesiveness of care. One single MS-DRG payment is intended to cover all hospital costs associated with treating a patient during his or her hospital stay, with the exception of physician charges associated with performing medical procedures, which are reimbursed through CPT codes and payments.

### ***Payment***

Payment refers to the amount paid to providers for specific procedures and supplies. Physician reimbursement under Medicare generally is based on a defined fee schedule (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 as a lump sum intended to cover all costs under a single MS-DRG payment. Reimbursement from commercial payors is typically based on a similar methodology but rates vary depending on the procedure performed, the hospital, the commercial payor, contract terms and other factors.

The American Hospital Association Coding Clinic provided guidance on the use of ICD-10 PCS codes for endobronchial valve procedures in Q3 2019. These ICD-10 PCS codes map to the MS-DRG classifications for Major Chest Procedures, with national average reimbursement rates between \$11,000 and \$30,000, for the year 2020, depending on co-morbidities and complications. Payment for Zephyr Valve is expected to, on average, be sufficient to cover costs of the procedure.

If a patient is positive for collateral ventilation following an assessment by the Chartis System, the patient is discharged the same day and the procedure will be billed as an outpatient procedure. The CPT code used to provide payment for the Chartis procedure, for patients who do not receive the Zephyr Valve due to collateral ventilation, maps to an Ambulatory Payment Classification, with a national average payment of \$5,148. If a patient receives the Zephyr Valve, there is no separate reimbursement for the Chartis System procedure; rather, the provider receives payment for the endobronchial valve procedures as described above.

The national Medicare average payment for physicians performing the endobronchial valve procedure is generally consistent with other complex bronchoscopic procedures.

### ***Commercial Payor and Government Program Coverage***

Coverage refers to decisions made by commercial third-party payors and government programs as to whether or not to provide their members access to and pay for specific procedures and related supplies, and if so, what conditions, such as specific diagnoses and clinical indications, are covered. Commercial payors typically base coverage decisions on reviews of clinical evidence presented in published peer-reviewed medical literature.

A majority of our patients are Medicare-eligible beneficiaries. Without a national coverage determination (NCD) or a local coverage determination (LCD), Medicare claims are managed by local carriers under Medicare's medical necessity requirement. We estimate that roughly 75% of the potential Zephyr Valve patient population are Medicare/Medicaid beneficiaries of which approximately 25% have managed Medicare/Medicaid and the remaining 50% have traditional Medicare/Medicaid. Approximately 25% of the potential Zephyr Valve patient population is under third-party commercial payor policies. A key element of our strategy remains to broaden our coverage by private third-party payor policies.

As of December 31, 2019, commercial payors such as Aetna, Humana, Priority Health and Emblem Health have issued positive coverage policies for endobronchial valve procedures. United Healthcare removed the endobronchial valve codes from their non-covered list, and, as such, no longer considers the procedure unproven or experimental. Other commercial payors, such as many plans in the Blue Cross Blue Shield family of plans, do not yet consider our solution medically necessary, but these same plans are approving pre-authorization requests on a case-by-case basis. We continue to engage with commercial payors to establish positive national coverage policies by highlighting our compelling and robust clinical data, unique patient selection tools, favorable cost profile to more invasive options, increased patient demand and support from global treatment recommendations for the management of COPD and emphysema.

#### ***Prior Authorization Approval Process***

A second key element of our reimbursement strategy includes leveraging our patient reimbursement support team and knowledge of the published data to assist patients and physicians in obtaining appropriate prior authorization approvals in advance of treatment. We believe our patient reimbursement support team is highly effective in working with patients and physicians to obtain appropriate prior authorizations for the Zephyr Valve treatment even when a non-coverage policy exists. We believe patients and providers will continue to benefit from support through the prior authorization process until widespread coverage is established across most commercial payors.

#### ***Reimbursement Outside of the United States***

Outside of the United States, reimbursement levels vary significantly by country and by patient. Reimbursement is obtained from a variety of sources, including government sponsors, hospital budgets or private health insurance plans, or combinations thereof. We have established reimbursement access in countries across Europe and Asia Pacific, including Australia, Germany, the Netherlands, South Korea, the United Kingdom and other countries.

#### ***Research, Development and Clinical Programs***

Our research and development team continues to design, develop and test new innovations to improve patient outcomes and expand our addressable market. We also work with external vendors in the design and testing of new technologies.

Since the early development of the Zephyr Valve, our company has produced a stream of innovations to increase the success rate of using the Zephyr Valve. This includes innovations in our airway sizing and delivery catheters, the introduction of new sizes of Zephyr Valves, improvements to the user interface of the Chartis System to accommodate a variety of anesthesia options and the StratX Platform to assist with patient selection and procedure planning.

We are in discussions with the FDA regarding the potential use of Zephyr Valves for the management of persistent air leaks. We believe there are approximately 7,000 patients who suffer from a persistent air leak per year in the United States that could benefit from treatment with Zephyr Valves.

Our pipeline of products that we are currently considering includes innovations in image analysis to support advanced patient selection and optimize patient outcomes, catheter technologies to improve valve deliverability and reduce procedure time and the AeriSeal system for addressing the needs of severe emphysema patients who are not eligible for Zephyr Valves due to collateral ventilation.

AeriSeal is a polymeric foam that can be delivered via a bronchoscope to a targeted region of the lung to induce an inflammatory response and reduce volume in the treated area. Early clinical trials have suggested the potential for effectiveness in the same range as Zephyr Valves. We intend to submit an IDE to the FDA for commencing a clinical trial with the AeriSeal system. We believe that positive results from this clinical trial would enable the treatment of patients with collateral ventilation, which would complement the screening of patients for Zephyr Valves. We have secured CE mark and Therapeutic Goods Administration approval in Australia for AeriSeal and have completed initial feasibility research. We further have funded a feasibility study using AeriSeal to expand the number of patients that can be treated with Zephyr Valves and are exploring additional studies. If successfully developed and approved, AeriSeal could further expand the addressable market of our solution.

For the year ended December 31, 2018, we incurred research and development expenses, including our clinical trials, of \$7.0 million.

## **Competition**

Our industry is highly competitive and subject to rapid change from the introduction of new products and technologies and other activities of industry participants.

We are positioning our solution as an alternative to existing treatments of severe emphysema. These treatments include medical management, other minimally invasive treatments, LVRS and lung transplantations. The major competitive products include the Spiration Valve System (Olympus Corporation) and the InterVapor System (Broncus Medical, Inc.; not approved for use in the United States). The Spiration Valve System is an endobronchial technology designed to offer patients with severe emphysema a minimally invasive treatment option for lung volume reduction by redirecting air away from diseased areas of the lung to healthier tissue so that patients may breathe easier. Like Zephyr Valves, the Spiration Valve System is indicated to treat patients with heterogeneous emphysema; however, the Spiration Valve System is contraindicated for patients with homogenous emphysema. We believe our solution competes favorably with the Spiration Valve System for several reasons, including the strength of our published clinical data, differentiated patient selection tools and our comprehensive technical and reimbursement support. InterVapor System offers a non-surgical and non-implant therapy developed for lung disease including emphysema and lung cancer where vapor ablation is simply the application of heated pure water to tissue.

Some of our current or future competitors may have several competitive advantages, including established relationships with pulmonologists who commonly treat patients with emphysema, significantly greater name recognition and significantly greater sales and marketing resources.

In addition to competing for market share, we also compete against these companies for personnel, including qualified sales and other personnel that are necessary to grow our business.

We believe the principal competitive factors in our market include the following:

- patient outcomes and adverse event rates;
- product safety, reliability and durability;
- patient experience;
- effective marketing to and education of patients, physicians and hospitals;
- acceptance by treating physicians and referral sources;
- physician learning curve;
- ease-of-use and reliability;

- patient recovery time and level of discomfort;
- economic benefits and cost savings;
- availability of coverage and adequate reimbursement; and
- strength of clinical evidence.

In addition to existing competitors, other companies may acquire or in-license competitive products and could directly compete with us. These competitors may also try to compete with us on price both directly, through rebates and promotional programs to high volume physicians and coupons to patients, and indirectly, through attractive product bundling with complementary products that offer convenience and an effectively lower price compared to the total price of purchasing each product separately. Larger competitors may also be able to offer greater customer loyalty benefits to encourage repeat use of their products and finance a sustained global advertising campaign to compete with commercialization efforts of our products. Our competitors may seek to discredit our products by challenging our short operating history or relatively limited number of scientific studies and publications. Smaller companies could also launch new or enhanced products and services that we do not offer and that could gain market acceptance quickly. Additionally, certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. As more companies develop new intellectual property in our market, there is the possibility of a competitor acquiring patents or other rights that may limit our ability to update our technologies and products which may impact demand for our products.

### **Intellectual Property**

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2019, we had 40 patent families in force worldwide. As of December 31, 2019, we had rights to 65 issued United States patents, 15 pending United States patent applications, 124 issued foreign patents and 15 pending foreign patent applications. Our most material foreign patents issued and patent applications pending are in the European Union, France, Germany, Japan and the United Kingdom. Our patents cover aspects of our current Zephyr Valve, loading system, airway sizing, EDC, Chartis System, AeriSeal and future product concepts. The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. Our patents expire between 2020 and 2037. We have applied to the U.S. Patent and Trademark Office (USPTO) seeking an extension for the term of a material Zephyr Valve patent from 2023 to 2027 under the Patent Term Extension which allows additional term to be added to a patent to compensate for the FDA approval process. Once a patent expires, the protection ends, and an invention enters the public domain; that is, anyone can commercially exploit the invention without infringing the patent.

There is no active patent litigation involving any of our patents and we have not received any notices claiming that our activities infringe a third party's patent.

We cannot guarantee that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents. Furthermore, numerous United States and foreign-issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to publish, there may be applications unknown to us, which may later result in issued patents that our existing or future products or technologies may be alleged to infringe.



There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. Adverse determinations in litigation could subject us to significant liabilities to third parties, require us to seek licenses from third parties or could prevent us from manufacturing, selling or using the product accused of infringement, any of which could severely harm our business. See "Risk Factors—Risks Related to our Intellectual Property" for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

We also rely upon trademarks to build and maintain the integrity of our brand. As of December 31, 2019, we had eight registered trademark filings, some of which may apply to multiple countries, and several pending trademark applications in various countries.

We also rely, in part, upon unpatented trade secrets, know-how and continuing technological innovation, and licensing arrangements, 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.

#### ***Cross-Licensing Agreement with Spiration/Olympus***

In January 2005, Emphasys Medical (Emphasys), a company we later acquired, entered into a cross-license agreement (Spiration Cross-License) with Spiration, Inc. (Spiration) (later acquired by Olympus Medical Systems Corp.). Since both companies were developing products in the same field, they entered into this agreement to minimize the risk of intellectual property disputes in the future and their associated cost. When we acquired Emphasys in 2009, we became the successor-in-interest to Emphasys' rights under the Spiration Cross-License. Under the agreement, each company non-exclusively licensed the other party to make, have made (solely for such other party), sell, offer for sale, import and export specific products under their respective patent portfolio at that time that covers such products or a method of use thereof. The license granted to us by Spiration is limited to devices where the outer perimeter of the device seals with the airway wall and the device allows fluid flow only through one or more openings in the device radially inward of such outer perimeter. It does not give us a license under Spiration's patent rights to valve devices that allow fluid flow only between the outer perimeter of the device and the airway wall. Similarly, the license granted to Spiration by us is limited to devices that allow fluid flow only between the outer perimeter of the device and the airway wall. It does not give Spiration a license under our patent rights to make or sell valve devices where the outer perimeter of the device seals with the airway wall and the device allows fluid flow only through one or more openings in the device radially inward of such outer perimeter. The licenses cannot be sublicensed. Furthermore, each license also includes a covenant not to sue the other party for infringement with respect to specified product elements, designs and features. The Spiration Cross-License can be terminated by either party upon 60 days' written notice to the other in the event certain patents are no longer owned by the other party or such patents are no longer in force; provided, that, the parties are required to negotiate in good faith during such 60-day notice period to attempt to enter into a replacement cross-license prior to such termination. Neither party may assign or otherwise transfer the Spiration Cross-License without the written consent of the other party, except in connection with certain change-of-control transactions. We do not have any relationship with Spiration other than with respect to this cross-license agreement.

#### **Manufacturing and Supply**

We manufacture all our products — valves, delivery catheters, balloon catheters and the Chartis System console — at our headquarters located at 700 Chesapeake Drive, Redwood City, California 94063 where we lease approximately 25,000 square feet of space. Our lease terminates on July 31, 2025. This facility supports production and distribution operations, including manufacturing, quality control, raw material and finished goods storage. We

have manufactured all our products at this facility for over 10 years and to date we have manufactured over 76,000 Zephyr Valves.

We rely on a combination of in-house processing and third-party suppliers for raw materials and components. We have supply agreements with a few critical suppliers while procuring most of our materials on a purchase order basis. Suppliers are routinely evaluated based on industry standards including on-site audits, as required, to be approved. We have a strict change control policy with our suppliers to ensure that no design or process changes are made without our prior approval. Based on our prior experience with such suppliers to manufacture products for commercialization both inside and outside the United States, we believe these suppliers are capable of continuing to meet our specifications and maintaining quality. Several components used in our devices rely on single source suppliers and we routinely prioritize, evaluate and qualify backup sources. We typically maintain several months of product in inventory however if one or more of our single source suppliers were to encounter a manufacturing issue or chooses to end supply, we estimate that some of our custom components could take between one and two years to qualify a second source supplier in all markets. The manufacture of AeriSeal, which is still in development, is completely outsourced to a contract manufacturer. The StratX Platform's QCT service is currently outsourced as well. We host the customer-facing web portal for the StratX Platform's QCT service while using a third-party cloud service provider to direct CT scan uploads from customers to qualified radiological image analysis providers.

We perform the final assembly, inspection, testing, packaging and product release testing for the Zephyr Valve, the EDC and Chartis System at our Redwood City facility. These products are sterilized using ethylene oxide at a qualified sterilization supplier in Los Angeles, California. In the United States, we generally ship products from our Redwood City facility to our direct sales territory managers, who deliver these products to our hospital customers. Once they are trained and proficient in the procedure, we may also sell our products directly to our hospital customers. Internationally, we ship our products to a qualified third-party logistics provider in the Netherlands who, in turn, may either ship directly to our customers in Europe, Australia and other international markets on a consignment basis or directly to our sales territory managers in these countries who then sell these products to our customers. We also ship from our Redwood City facility to distributors in Asia Pacific and other international markets.

Our manufacturing and distribution operations are subject to regulatory requirements of the FDA's QSR for medical devices sold in the United States, set forth in 21 CFR part 820, and the EU's MDD for medical devices marketed in the European Union. We are also subject to applicable local regulations relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment and remediation of hazardous substances.

The FDA monitors compliance with the QSR through periodic inspections of our facilities, which may include inspection of our suppliers' facilities as well. Our European Union Notified Body, British Standards Institute (BSI), monitors compliance with the MDD requirements through both annual scheduled audits and periodic unannounced audits of our manufacturing facilities as well as our contract third-party suppliers' facilities.

Our failure, or the failure of our third-party suppliers, to maintain acceptable quality requirements could result in the shutdown of our manufacturing operations or the recall of our products. If one of our suppliers fails to maintain acceptable quality requirements, we may have to qualify a new supplier, which could adversely affect manufacturing of our products and result in manufacturing delays as well as have a material adverse effect on our business and financial condition.

Our quality management system in our Redwood City manufacturing facility is currently ISO 13485:2016 certified, MDD certified and licensed by the California Department of Public Health (CDPH) Food and Drug Branch. Our manufacturing facility is an FDA-registered medical device establishment.

The FDA conducted a total of two establishment inspections of our manufacturing facility in 2014 and 2016. We believe that we are in compliance, in all material respects, with all applicable FDA and QSR requirements.

Manufacturing of the materials and components of our products are provided by approved suppliers, all of which are single source suppliers of key components, sub-assemblies and materials. The suppliers for the products are evaluated, qualified and approved through a stringent supplier management program, which includes various evaluations, assessments, qualifications, validations, testing and inspection to ensure the supplier can meet acceptable quality requirements. We implement a strict change control policy with our key suppliers to ensure that no component or process changes are made without our prior approval.

Order quantities and lead times for components purchased from suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary depending on the size of the order, time required to manufacture and test the components, specific supplier requirements and current market demand for the components, sub-assemblies and materials. We perform assembly, testing, inspection and final product release activities for our products.

## **Government Regulation**

### ***United States Food and Drug Administration***

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938 and its implementing regulations (FDCA), as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export and post-marketing surveillance.

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

### ***Device Classification***

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 control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices (General Controls), which require compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse events and malfunctions, and as appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device (Special Controls). These Special Controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA

application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The Zephyr Valve is a Class III device that has received FDA PMA approval.

### ***The Investigational Device Exemption Process***

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and Institutional Review Board (IRB) approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. There can be no assurance that submission of an IDE application will result in the ability to commence clinical trials, and although the FDA's approval of an IDE application allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibition of promotion, recordkeeping, and reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;

- side effects or device malfunctions of similar products already in the market that change the FDA’s view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- IRBs and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- third-party investigators are disqualified by the FDA;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records and reports of sponsors of clinical investigations;
- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or third-party clinical investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or
- the FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness.

### ***The PMA Approval Process***

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

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

- the device may not be shown safe or effective to the FDA’s satisfaction;

- the data from pre-clinical studies or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

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

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

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study (PAS) or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. We are subject to certain PAS requirements under our PMA for the Zephyr Valve. PAS reports for the Zephyr Valve Registry study are required every six months for the first two years of the study and annually thereafter. PAS reports for the LIBERATE extension study are required annually. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

#### ***Pervasive and Continuing Regulation***

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- medical device reporting regulations (MDRs), which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

- medical device recalls, which require that manufacturers report to the FDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device that may present a risk to health; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the CDPH. The FDA and CDPH have broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our third-party suppliers. Additionally, our Notified Body, the BSI, regularly inspects our manufacturing, design and operational facilities to ensure ongoing ISO 13485 compliance in order to maintain our CE mark. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory bodies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or PMA approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or PMA approvals that have already been granted; and
- criminal prosecution.

#### *European Union*

Our portfolio of products is regulated in the European Union as a medical device per the European Union Medical Devices Directive (Council Directive 93/42/EEC) (MDD). The MDD sets out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE mark which shows that the device has a Certificate de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD within their jurisdiction. The means for achieving the requirements for the CE mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks, similar to the United States system. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard. Our current CE mark is issued by BSI.

#### *Health Insurance Portability and Accountability Act*

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), established federal protection for the privacy and security of health information. Under HIPAA, the United States Department of Health and Human Services (HHS), has issued regulations to protect the privacy and security of PHI used or disclosed by “Covered Entities,” including certain healthcare providers, health plans and healthcare clearinghouses, and their respective “Business Associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered

entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and certain healthcare providers. The HIPAA privacy regulations protect medical records and other PHI by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical and technical safeguards and the adoption of written security policies and procedures. In addition, HIPAA requires Covered Entities to execute Business Associate Agreements with their Business Associates and subcontractors, who provide services for or on behalf of Covered Entities. Business Associates have a corresponding obligation to maintain appropriate Business Associate Agreements under HIPAA. In addition, companies that would not otherwise be subject to HIPAA may become contractually obligated to follow HIPAA requirements through agreements with Covered Entities and Business Associates, and some of our customers may require us to agree to these provisions.

In addition, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to \$250,000 and permit injured parties to sue for damages. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues and potentially exposing us to additional expense, adverse publicity and liability. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely, and new privacy and security laws in this area are evolving. Requirements of these laws and penalties for violations vary widely.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, and similar state laws, we may be subject to significant penalties, including civil, criminal and administrative penalties, fines, imprisonment and exclusion from participation in federal or state healthcare programs, and the curtailment or restructuring of our operations. In addition, HITECH created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to Business Associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

### **U.S. Federal, State and Foreign Fraud and Abuse Laws**

The federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

#### ***Anti-Kickback Statutes***

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare or 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 definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. 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 businesses, the statute has been violated. 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. Violations can also result in criminal penalties, including criminal fines of up to \$100,000 and imprisonment of up to ten years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and



Medicaid. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act) to a stricter standard such that 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. Further, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (FCA).

There are a number of statutory exceptions and regulatory “safe harbors” protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance to offer protection. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the HHS Office of the Inspector General (OIG).

Many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only government healthcare programs, and may apply to payments made directly by the patient.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

### ***Federal False Claims Laws***

The federal false claims laws, including the FCA, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payor and not only a federal healthcare program.

When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus significant civil fines and penalties. As part of a settlement, the government may require the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the FCA. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the FCA to assert liability on the basis of kickbacks, or in instances in which manufacturers have provided billing or coding advice to providers that the government considered to be inaccurate. In these cases, the manufacturer faces liability for “causing” a false claim. In addition, the federal government has prosecuted companies under the FCA in connection with off-label promotion of products. Our activities, including those relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products (such as our patient reimbursement support programs) and the sale and marketing of our products, may be subject to scrutiny under these laws.

While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the FCA or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

### ***Civil Monetary Penalties***

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.

### ***Open Payments***

The Physician Payments Sunshine Act (Open Payments), enacted as part of the Affordable Care Act, requires certain pharmaceutical, medical device and medical supply manufacturers covered by Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS: payments and transfers of value to physicians, certain other healthcare providers, teaching hospitals, and applicable manufacturers and group purchasing organizations, as well as to report annually ownership and investment interests held by physicians and their immediate family members. 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. We are subject to Open Payments and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

### ***Foreign Corrupt Practices Act***

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

### ***International Laws***

In Europe, various countries have adopted anti-bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

For instance, in the United Kingdom, under the U.K. Bribery Act of 2010 (Bribery Act), a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act. An individual found in violation of the U.K. Bribery Act of 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the access, use and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

### ***United States Centers for Medicare and Medicaid Services***

Medicare is a federal program administered by CMS through fiscal intermediaries and carriers. Available to individuals age 65 or over, and certain other individuals, the Medicare program provides, among other things,

healthcare benefits that cover, within prescribed limits, the major costs of most medically necessary care for such individuals, subject to certain deductibles and copayments.

CMS has established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a healthcare procedure furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. Any changes in federal legislation, regulations and policy affecting CMS coverage and reimbursement relative to the procedure using our products could have a material effect on our performance. While no NCD or LCD exists for endobronchial valves currently, CMS could develop an NCD, or one or more Medicare contractors could develop an LCD that either restricts coverage or restricts the patient population deemed appropriate for the treatment.

CMS also administers the Medicaid program, a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement vary from state to state and is subject to each state's budget restraints. Changes to the availability of coverage, method or level of reimbursement for relevant procedures may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

All CMS programs are subject to statutory and regulatory changes, retroactive and prospective rate adjustments, administrative rulings, interpretations of policy, intermediary determinations, and government funding restrictions, all of which may materially increase or decrease the rate of program payments to healthcare facilities and other healthcare providers, including those paid for Zephyr Valve treatments.

### ***United States Health Reform***

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future products. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. 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. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance and delaying the implementation of certain fees mandated by the Affordable Care Act. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

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 CMS 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 2029 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS 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 believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

### **Employees**

As of December 31, 2019, we had 180 full-time employees. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that we have good relations with our employees.

### **Facilities**

We currently lease approximately 25,000 square feet for our corporate headquarters located in Redwood City, California under a lease agreement that terminates in 2025. This facility supports production and distribution operations, including manufacturing, quality control, raw material and finished goods storage. We also lease office space in Neuchâtel, Switzerland. We believe that these facilities are sufficient to meet our current and anticipated needs in the near term and that additional space can be obtained on commercially reasonable terms as needed.

### **Legal Proceedings**

From time to time we may become involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. We may from time to time receive letters from third parties alleging patent infringement, violation of employment practices or trademark infringement, and we may in the future participate in litigation to

defend ourselves. We cannot predict the results of any such disputes, and despite the potential outcomes, the existence thereof may have an adverse material impact on us due to diversion of management time and attention as well as the financial costs related to resolving such disputes.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth information concerning our executive officers and directors as of December 31, 2019:

Name	Age	Position(s)
<b>Executive Officers</b>		
Glendon E. French	57	President, Chief Executive Officer and Director
Derrick Sung, Ph.D.	47	Chief Financial Officer
Geoffrey Beran Rose	46	Chief Commercial Officer
<b>Non-Employee Directors</b>		
Charles Chon	45	Director
Richard Ferrari	66	Director
Daniel Florin <sup>(4)</sup>	55	Director
Staffan Lindstrand	57	Director
Dana G. Mead, Jr.	60	Director and Chairperson of the Board
Michael Matly, M.D.	38	Director
Rodney Perkins, M.D.	83	Founder and Director
Stephen Salmon	59	Director
Oern Stuge, M.D.	65	Director

(1) Member of the audit committee

(2) Member of the compensation committee

(3) Member of the nominating and corporate governance committee

(4) Mr. Florin was appointed as a director on January 17, 2020.

### Executive Officers

*Glendon E. French* has served as our President, Chief Executive Officer and as a member of our board of directors since December 2014. From January 2014 to November 2014, Mr. French served as Chief Executive Officer and as a director of ApniCure, a medical device company. From October 2010 to December 2012, Mr. French served as President, Pulmonary Endoscopy for Boston Scientific Corporation, a medical device company. From December 2003 to October 2010, Mr. French served as President and Chief Executive Officer and as a director of Asthmatx, Inc., a medical device company. Mr. French serves as the Executive Chairman of the board of directors of Levita Magnetics International Corp., a medical device company. Mr. French holds a B.A. in History from Dartmouth College and an M.B.A. from the Wharton School at the University of Pennsylvania. We believe that Mr. French is qualified to serve as a member of our board of directors because of his extensive leadership experience and knowledge of the medical device industry.

*Derrick Sung, Ph.D.* has served as our Chief Financial Officer since May 2019. From May 2015 to May 2019, Dr. Sung served as the Executive Vice President of Strategy and Corporate Development for iRhythm Technologies, Inc., a digital healthcare and medical technology company. From February 2008 to April 2015, Dr. Sung was the senior equity research analyst covering the medical devices sector for Sanford C. Bernstein & Co., LLC, a subsidiary of AllianceBernstein L.P. From 2004 to 2008, he served as Director of Marketing and Business Development in the Neuromodulation division of Boston Scientific Corporation. From 2000 to 2004, Dr. Sung was a management consultant at The Boston Consulting Group, a business consulting firm. Dr. Sung holds a Ph.D. in Bioengineering from U.C. San Diego, an M.B.A. from San Diego State University and a B.S. in Mechanical Engineering from Stanford University.

*Geoffrey Beran Rose* has served as our Chief Commercial Officer since January 2020. From December 2014 to January 2020, Mr. Rose served as our Vice President, Marketing and Business Development. From August 2013 to December 2014, Mr. Rose served as Global Group Marketing Director for Boston Scientific Corporation. From August 2006 to August 2013, Mr. Rose served as a director of strategy within research and development and clinical organizations of Boston Scientific Corporation. Mr. Rose holds a B.A. from Yale University and an M.B.A. from the MIT Sloan School of Management.

#### ***Non-Employee Directors***

*Charles Chon* has served on our board of directors since April 2019. Mr. Chon is a Partner and Managing Director of Ally Bridge Group (ABG), a healthcare-focused investment group, where Mr. Chon leads the group's investing efforts in medical technologies. Before joining ABG in 2013, Mr. Chon was in public equity research for more than 13 years on both the sell-side and buy-side covering healthcare and, more specifically, medical technologies. This includes experiences with Janchor Partners Limited, a long-short fund based in Hong Kong, from 2012 to 2013, Stifel Nicolaus & Co., a global investment bank and financial services company, from 2010 to 2012, and Goldman Sachs Group, Inc., another global investment bank and financial services company, from 2004 to 2009. Mr. Chon holds a CFA designation, and an M.B.A. in healthcare management from Boston University and a B.A. in Chemistry from Amherst College. We believe that Mr. Chon is qualified to serve as a member of our board of directors because of his extensive experience in public equities research and working with medical technology companies.

*Richard Ferrari* has served on our board of directors since March 2007. Mr. Ferrari is the Co-Founder and Managing Director of De Novo Ventures, a healthcare investment firm dedicated to medical devices and bio-technology. Mr. Ferrari also serves as a faculty member of the Stanford Biodesign Emerging Entrepreneurs Forum, as well as a board member for the Stanford Coulter Foundation for Translational Medicine. From October 1995 to May 1999, Mr. Ferrari co-founded and served as the Chief Executive Officer of CardioThoracic Systems, Inc., a surgery medical technology and device company. From January 1990 to June 1995, Mr. Ferrari served as the CEO of Cardiovascular Imaging Systems, a developer of ultrasound imaging. Mr. Ferrari holds a B.S. from Ashland University and an M.B.A. from the University of South Florida. We believe that Mr. Ferrari is qualified to serve as a member of our board of directors because of his technical knowledge, extensive leadership experience at medical technology companies and the historical knowledge and continuity he brings to our board of directors.

*Daniel Florin* has served as a member our board of directors since January 2020. Since July 2019, Mr. Florin has served as Executive Vice President of Zimmer Biomet Holdings Inc., a medical device company. From June 2015 to July 2019, Mr. Florin served as Zimmer BioMet's Executive Vice President and Chief Financial Officer. From July 2017 to December 2017, Mr. Florin served as Zimmer Biomet's Interim Chief Executive Officer. From June 2007 to June 2015, Mr. Florin served as Senior Vice President and Chief Financial Officer at Biomet, Inc. (prior to Biomet's merger with Zimmer). From January 2001 to May 2007, Mr. Florin served as Vice President and Corporate Controller of Boston Scientific Corporation. Mr. Florin has served as a board member at AtriCure, Inc. since December 2019. Mr. Florin holds a B.A. with a concentration in Accounting from the University of Notre Dame and an M.B.A. from Boston University. We believe that Mr. Florin is qualified to serve as a member of our board of directors because of his extensive experience in the medical device industry.

*Staffan Lindstrand* has served on our board of directors since February 2010. Mr. Lindstrand is a Partner of HealthCap, a venture capital firm investing in life science companies. Mr. Lindstrand currently serves on the boards of directors of Orexo AB, a Nasdaq Stockholm-listed specialty pharmaceutical company, Doctrin AB, a healthcare technology platform, and Pactumize, a legal technology company, as well as other private company boards. Mr. Lindstrand also previously served on the board of Aerocrine AB, a previously Nasdaq Stockholm-listed medical device company. From December 1986 to September 1997, Mr. Lindstrand served as a Vice President at ABB Aros Securities AB in Sweden, a brokerage and financial advisory firm. Mr. Lindstrand holds an M.Sc. in Engineering from the KTH Royal Institute of Technology of Stockholm. We believe that Mr. Lindstrand is qualified to serve as a member of our board of directors because of his experience with medical device and life science companies, his service on public and private company boards and the historical knowledge and continuity he brings to our board of directors.

*Dana G. Mead, Jr.* has served as a member of our board of directors since February 2010 and has served as our Chairman since October 2019. Since May 2019, Mr. Mead has served as the Chief Executive Officer, President and director of HeartFlow, Inc., a medical technology company. From November 2016 to May 2019, Mr. Mead served as President and Chief Executive Officer of Beaver-Visitec International, Inc., a surgical device developer and manufacturer. From June 2005 to November 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 and the board of HeartFlow, Inc., Mr. Mead has served on the board of directors of Inspire Medical Systems since July 2008 and the board of directors of Intersect ENT, Inc. since January 2006, 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 that Mr. Mead is qualified to serve as a member of our board of directors because of his service on other medical technology company boards, his broad experience in the healthcare industry and the historical knowledge and continuity he brings to our board of directors.

*Michael Matly, M.D.* has served on our board of directors since March 2016. Dr. Matly is a Managing Director at Montreux Growth Partners, a private investment firm focused on health services and technology companies. From September 2009 to June 2012, Dr. Matly led Business Development and New Ventures at the Mayo Clinic Center for Innovation, a center within The Mayo Clinic, a nonprofit academic medical center. Dr. Matly holds an M.D. from the Mayo Clinic, an M.B.A. from Harvard Business School, and a B.S. from Cornell University. We believe that Dr. Matly is qualified to serve as a member of our board of directors because of his extensive medical knowledge, his experience in the medical technology field and his experience serving on the board of public and private companies.

*Rodney Perkins, M.D.* is our founder and has served on our board of directors since March 1996. Dr. Perkins previously served as our Chief Executive Officer from March 1996 to December 1999, October 2000 to September 2001, and July 2013 to June 2014; Chairman of our board of directors from June 1996 until October 2019; Chief Financial Officer from March 1996 to November 2003; and President from March 1996 to December 1999, and March 2006 to July 2009. Dr. Perkins is an internationally known otologic surgeon who has participated actively in the development of multiple successful medical device companies. He is the founder of the California Ear Institute and a Professor of Surgery at Stanford University. Dr. Perkins holds an M.D. from The Indiana University and completed his surgical residency at The Stanford University School of Medicine. We believe that Dr. Perkins is qualified to serve as a member of our board of directors because of his extensive experience with medical technology companies, his service on public and private company boards and the historical knowledge and continuity he brings to our board of directors.

*Stephen Salmon* has served as a member our board of directors since June 2007. Since June 2005, Mr. Salmon has served as a partner at LVP Life Science Ventures III, L.P., a private investment fund focused on healthcare companies. Mr. Salmon previously served as the Vice President, Research & Development, at Boston Scientific Corporation and held executive positions within several medical device companies. Mr. Salmon has authored or co-authored 34 U.S. patents. Mr. Salmon holds a B.S. in Chemical Engineering from the University of Maine. We believe Mr. Salmon is qualified to serve as a member of our board of directors because of his extensive experience working for and advising medical device research and development companies and the historical knowledge and continuity he brings to our board of directors.

*Oern R. Stuge, M.D.* has served as a member of our board of directors since October 2014. Since October 2013, Dr. Stuge has served as Executive Chairman of our subsidiary, PulmonX International Sàrl. Since January 2011, Dr. Stuge has been Chairman of Orsco Lifesciences AG, a management firm specializing in medical technology companies. Dr. Stuge previously served as our interim Chief Executive Officer from June 2014 to December 2014. From May 1998 to December 2009, Dr. Stuge served in various positions, including as Senior Vice-President, at Medtronic, Inc., a medical device company. Dr. Stuge currently serves on the board of GI Dynamics, Inc., a publicly traded medical device company. Dr. Stuge is also currently Chairman of Mainstay Medical Limited, a Euronext Paris-listed and Irish Stock Exchange-listed medical device company and Lumenis Limited, formerly a Nasdaq-listed medical company. Dr. Stuge holds an M.D. from the University of Oslo, Norway, an M.B.A. from IMD and an INSEAD Certification in Corporate Governance. We believe that Dr. Stuge is qualified to serve as a member of our



board of directors because of his extensive experience in sales, management and operations in the medical device industry and his service on the boards of public and private medical device and technology companies.

### **Family Relationships**

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

### **Board Composition and Election of Directors**

Our board of directors currently consists of ten members. Each director is currently elected to the board of directors for a one-year term, to serve until the election and qualification of a successor director at our annual meeting of stockholders, or until the director's earlier removal, resignation or death.

Certain of our directors currently serve on the board of directors pursuant to the voting provisions of a voting agreement between us and several of our stockholders. Under the terms of this voting agreement, the stockholders who are party to the voting agreement have agreed to vote their respective shares so as to elect: (1) one director to be designated by Montreux Equity Partners, who is currently Dr. Matly; (2) one director to be designated by De Novo Ventures, who is currently Mr. Ferrari; (3) one director to be designated by Latterell Venture Partners, who is currently Mr. Salmon; (4) one director to be designated by HealthCap V L.P., who is currently Mr. Lindstrand; (5) one director designated by KPCB Holdings, Inc., who is currently Mr. Mead; (6) one director designated by ABG-Pulmonx Limited, who is currently Mr. Chon; (7) one director to be our current Chief Executive Officer, who is currently Mr. French; (8) one director elected by the holders of our common stock, who is currently Dr. Perkins; and (9) two directors who are industry experts designated by the other directors, who is currently Dr. Stuge and Mr. Florin. This agreement will terminate upon the completion of this offering, after which there will be no further contractual obligations regarding the election of our directors.

### **Classified Board of Directors**

In accordance with our amended and restated certificate of incorporation, which will become effective in connection with the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- Class I, which will consist of \_\_\_\_\_, whose term will expire at our first annual meeting of stockholders to be held after the completion of this offering;
- Class II, which will consist of \_\_\_\_\_, whose term will expire at our second annual meeting of stockholders to be held after the completion of this offering; and
- Class III, which will consist of \_\_\_\_\_, whose term will expire at our third annual meeting of stockholders to be held after the completion of this offering.

Our amended and restated bylaws, which will become effective in connection with the completion of this offering, will provide that the authorized number of directors may be changed only by resolution approved by a majority 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 entitled "Description of Capital Stock—Anti-Takeover Provisions—Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation and Bylaws to be in Effect Upon the Completion of this Offering."

## Director Independence

Our board of directors has undertaken a review of the independence of the 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 such director's background, employment and affiliations, including family relationships, our board of directors determined that \_\_\_\_\_, representing \_\_\_\_\_ of our ten directors following the completion of this offering, are "independent directors" as defined under the listing standards of the Nasdaq Global Market. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in "Certain Relationships and Related Party Transactions."

## Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. Each of the audit committee, the compensation committee and the nominating and corporate governance committee will operate under a written charter that will be approved by our board of directors in connection with this offering. From time to time, our board of directors may establish other committees to facilitate the management of our business.

### *Audit Committee*

Our audit committee consists of three directors, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. Our board of directors has determined that each of our audit committee members satisfies the independence requirements for audit committee members under the listing standards of the \_\_\_\_\_ and Rule 10A-3 of the Exchange Act. Each member of our audit committee meets the financial literacy requirements of the listing standards of the Nasdaq Global Market. \_\_\_\_\_ is the chairperson of the audit committee and our board of directors has determined that \_\_\_\_\_ is an audit committee "financial expert" as defined by Item 407(d) of Regulation S-K under the Securities Act of 1933, as amended (Securities Act). The principal duties and responsibilities of our audit committee include, among other things:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes its internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit services, other than de minimis non-audit services, to be performed by the independent registered public accounting firm.

Our audit committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

### ***Compensation Committee***

Our compensation committee consists of \_\_\_\_\_ directors, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, each of whom our board of directors has determined is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act. \_\_\_\_\_ is the chairperson of the compensation committee. The composition of our compensation committee meets the requirements for independence under current listing standards of the Nasdaq Global Market and current SEC rules and regulations. The principal duties and responsibilities of our compensation committee include, among other things:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers, including evaluating the performance of our chief executive officer and, with his assistance, that of our other executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- administering our equity and non-equity incentive plans;
- reviewing and approving, or recommending that our board of directors approve, incentive compensation and equity plans; and
- reviewing and establishing general policies relating to compensation and benefits of our employees and reviewing our overall compensation philosophy.

Our compensation committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

### ***Nominating and Corporate Governance Committee***

Our nominating and corporate governance committee consists of \_\_\_\_\_ directors, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. \_\_\_\_\_ is the chairperson of the nominating and corporate governance committee. The composition of our nominating and corporate governance committee meets the requirements for independence under current listing standards of the Nasdaq Global Market and current SEC rules and regulations. The nominating and corporate governance committee's responsibilities include, among other things:

- identifying, evaluating and selecting, or recommending that our board of directors approve, nominees for election to our board of directors and its committees;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and

- overseeing an annual evaluation of the board’s performance.

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

### Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a Code of Business Conduct and Ethics (Code of Conduct) applicable to all of our employees, executive officers, and directors. Following the completion of this offering, the Code of Conduct will be available on our website. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements with respect to our executive officers and directors, will be disclosed on our website.

### Compensation Committee Interlocks and Insider Participation

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 of any entity that has one or more executive officers serving on our board of directors or compensation committee. None of the members of our compensation committee is an officer or employee of our company, nor have they ever been an officer or employee of our company.

### Non-Employee Director Compensation

The following table sets forth information regarding the compensation earned for service on our board of directors during the year ended December 31, 2019 by our non-employee directors. Glendon E. French, our Chief Executive Officer, is also a member of our board of directors, but did not receive any additional compensation for service as a director. Mr. French’s compensation as an executive officer is set forth below under “Executive Compensation—2019 Summary Compensation Table.”

Name <sup>(1)</sup>	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(2)</sup>	All Other Compensation (\$)	Total (\$)
Charles Chon	\$ —	\$ —	\$ —	\$ —
Richard Ferrari	—	—	—	—
Daniel Florin	—	13,548	12,500 <sup>(3)</sup>	26,048
Staffan Lindstrand	—	—	—	—
Dana G. Mead, Jr.	15,000	13,548	—	28,548
Michael Matly, M.D.	—	—	—	—
Rodney Perkins, M.D.	—	14,994	—	14,994
Stephen Salmon	—	—	—	—
Oern Stuge, M.D.	—	2,269	72,075 <sup>(4)</sup>	74,344

(1) All amounts presented in the Non-Employee Director Compensation table are expressed in U.S. dollars, except as listed in footnote 3 below.

(2) Amounts shown in this column do not reflect dollar amounts actually received by our non-employee directors. Instead, these amounts reflect the aggregate grant date fair value of each stock option granted in 2018, computed in accordance with the provisions of FASB ASC Topic 718. Methodology used in the calculation of these amounts are included in Note 11 to our consolidated financial statements included in this prospectus. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our non-employee directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(3) Consists of \$12,500 paid to Mr. Florin under the terms of a consulting agreement, which was terminated on his election to our board.

(4) Consists of: (i) \$12,056 paid to Dr. Stuge for his services as Executive Chairman of PulmonX International S à rl and (ii) \$60,020 paid to Orsco Life Sciences AG, a consulting entity owned by Dr. Stuge, for consulting services rendered to PulmonX International Sàrl. All amounts payable to Dr. Stuge in 2019 were paid in Swiss francs. The exchange rate used for the purpose of the Non-Employee Director Compensation Table was as follows: (i) for payments in January 2019, 0.9905 Swiss francs to 1 U.S. dollar, (ii) for payments in February 2019, 0.9934 Swiss francs to 1 U.S. dollar, (iii) for payments in March 2019, 1.0003 Swiss francs to 1 U.S. dollar, (iv) for payments in April 2019, 0.9955 Swiss francs to 1 U.S. dollar, (v) for payments in May, 1.0202 Swiss francs to 1 U.S. dollar, (vi) for payments in June, 1.0068 Swiss francs to 1 U.S. dollar, (vii) for payments in July 2019, 0.9781 Swiss francs to 1 U.S. dollar, (viii) for payments in August 2019, 0.9909 Swiss francs to 1 U.S. dollar, (ix) for payments in September 2019, 0.9837 Swiss francs to 1 U.S. dollar, (x) for October, 0.9928 Swiss francs to 1 U.S. dollar, (xi) for payments in November 2019, 0.9947 Swiss francs to 1 U.S. dollar and (xii) for payments in December 2019, 0.9990 Swiss francs to 1 U.S. dollar, based on the average exchange rates published by the Federal Reserve Bank in 2019.

We currently reimburse our directors for their reasonable out-of-pocket expenses in connection with attending board of directors and committee meetings. From time to time, we have granted stock options to certain of our non-employee directors as compensation for their services.

In June 2019, we granted Dr. Stuge an option to purchase 30,000 shares of common stock with an exercise price of \$0.14 per share, vesting monthly over one year.

In June 2019, we granted Dr. Perkins an option to purchase 200,000 shares of common stock with an exercise price of \$0.14 per share, of which 100,000 were fully vested as of the date of grant and 100,000 vest monthly over one year.

In October 2019, we granted Mr. Florin an option to purchase 60,000 shares of common stock with an exercise price of \$0.21 per share, vesting monthly over one year, which vesting will terminate upon the closing of this offering.

In October 2019, we granted Mr. Mead an option to purchase 60,000 shares of common stock with an exercise price of \$0.21 per share, vesting monthly over one year, which vesting will terminate upon the closing of this offering.

Commencing in October 2019 and until the closing of this offering, we are paying Mr. Mead \$5,000 per month for service as Chairman of our board of directors.

#### **Non-Employee Director Compensation Policy**

We intend to adopt a non-employee director compensation policy, pursuant to which our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors.

## EXECUTIVE COMPENSATION

Our named executive officers, consisting of our principal executive officer and our two other most highly compensated officers for our fiscal year ended December 31, 2019, were:

- Glendon E. French, Chief Executive Officer and Director;
- Derrick Sung, Ph.D., Chief Financial Officer; and
- Geoffrey Beran Rose, Chief Commercial Officer.

### Summary Compensation Table

The following table sets forth all of the compensation awarded to, or earned by or paid to our named executive officers during 2019.

Name and Principal Position	Salary	Bonus	Option Awards <sup>(1)</sup>	Non-Equity Incentive Plan Compensation <sup>(2)</sup>	All Other Compensation <sup>(3)</sup>	Total
Glendon E. French <i>Chief Executive Officer</i>	\$ 412,000		\$ 546,326	\$ 152,110	\$ 642	\$ 1,111,078
Derrick Sung, Ph.D. <i>Chief Financial Officer</i>	196,591		186,600	45,363	348	428,902
Geoffrey Beran Rose <i>Chief Commercial Officer</i>	272,600		137,163	62,902	642	473,307

(1) These columns reflect the aggregate grant date fair value of options without regard to forfeitures granted during the year measured pursuant to Financial Accounting Standards Board Accounting Standards Codification Topic 718 (ASC 718). Assumptions used in the calculation of these amounts are included in Note 11 to our Consolidated Financial Statements included in this prospectus. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) Represents payments upon the achievement of 2019 corporate goals as well as individual objectives, which were paid in January 2020. Our corporate goals included revenue growth, reimbursement progress and clinical and regulatory milestones.

(3) Amounts reported represent life insurance premiums paid by us on behalf of the named executive officer.

## Outstanding Equity Awards as of December 31, 2019

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2019. All awards were granted under our 2010 Stock Plan. See “—Employment, Severance, and Change in Control Agreements” for a description of vesting acceleration applicable to stock options held by our named executive officers.

Name	Grant Date	Option Awards				
		Vesting Commencement Date	Number of Securities Underlying Exercisable Options	Number of Securities Underlying Unexercisable Options	Option Exercise Price	Option Expiration Date
Glendon E. French	2/15/2015	12/10/2014	7,094,554 <sup>(1)(2)</sup>	—	\$0.14	2/14/2025
	2/15/2015	12/10/2014	644,960 <sup>(2)(3)</sup>	—	0.14	2/14/2025
	12/2/2015	12/10/2014	938,655 <sup>(1)(2)</sup>	—	0.15	12/1/2025
	12/2/2015	12/10/2014	111,306 <sup>(2)(3)</sup>	—	0.15	12/1/2025
	6/1/2016	6/1/2016	833,047 <sup>(2)(4)</sup>	—	0.15	5/31/2026
	6/1/2016	6/1/2016	75,731 <sup>(2)(3)</sup>	—	0.15	5/31/2026
	2/6/2017	2/6/2017	413,043 <sup>(2)(4)</sup>	—	0.13	2/5/2027
	2/6/2017	2/6/2017	37,550 <sup>(2)(3)</sup>	—	0.13	2/5/2027
	10/21/2019	10/2/2019	2,350,000 <sup>(2)(4)</sup>	—	0.21	10/20/2029
Derrick Sung, Ph.D.	6/27/2019	<sup>(5)</sup>	762,199 <sup>(2)(5)</sup>	—	0.14	6/26/2029
Geoffrey Beran Rose	2/15/2015	12/16/2014	714,285 <sup>(1)(2)</sup>	—	0.14	2/14/2025
	12/2/2015	12/16/2014	222,612 <sup>(1)(2)</sup>	—	0.15	12/1/2025
	6/1/2016	12/16/2014	151,463 <sup>(1)(2)</sup>	—	0.15	5/31/2026
	2/6/2017	12/16/2014	75,099 <sup>(1)(2)</sup>	—	0.13	2/5/2027
	10/21/2019	10/2/2019	590,000 <sup>(2)(6)</sup>	—	0.21	10/20/2029

- (1) 1/4th of the total shares subject to this option will vest one year after the vesting commencement date and the balance of the shares subject to this option will vest in a series of thirty-six successive equal monthly installments from the first anniversary of the vesting commencement date, subject to continuous service through each such date. As of December 31, 2019, all of the shares are vested.
- (2) This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by the Company upon the termination of the service of the named executive officer.
- (3) 100% of the total shares subject to this option shall accelerate and become fully vested upon action of the Board or a Change of Control (as defined in that certain Executive Employment Agreement by and between the Company and Mr. French, dated December 10, 2014) that represents an enterprise value for the Company that is at least \$500 million. As of December 31, 2019, no shares are vested.
- (4) 1/48th of the total shares subject to this option will vest monthly measured from the vesting commencement date, subject to continuous service through each such date. As of December 31, 2019, 728,916, 292,572 and 97,916 shares are vested, respectively.
- (5) This option shall commence vesting on the earlier of (i) May 6, 2020 or (ii) the closing of the Company's initial public offering ("IPO") and will vest monthly over three years (1/36th per month). If however on May 6, 2020 the Company has not closed its IPO and the Company is in bona fide discussions regarding the sale of the Company (such determination of bona fide discussions to be made by the Board of Directors in good faith), then this option shall terminate and not vest in any part assuming those discussions result in the sale of the Company. However, if the bona fide discussions regarding the sale of the Company come to a clear end (such determination to be made by the Board of Directors in good faith) or extend more than 180 days beyond May 6, 2020 without the sale of the Company then the Option will commence vesting back on May 6, 2020 and will vest monthly over three years (1/36 per month). As of December 31, 2019, no shares are vested.
- (6) 1/48th of the total shares subject to this option will vest monthly measured from the vesting commencement date, subject to continuous service through each such date. As of December 31, 2019, 24,583 shares are vested.

## Emerging Growth Company Status

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). As an emerging growth company we will be exempt from certain requirements related to executive compensation, including, but not limited to, the requirements to hold a nonbinding advisory vote on executive compensation and to

provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

## **Employment, Severance, and Change in Control Agreements**

### ***Employment Agreement with Mr. French***

We entered into an employment agreement with Mr. French in December 2014. The agreement provides for an initial base salary of \$375,000 and target annual bonus of 40% of base salary. More current information regarding Mr. French's compensation is set forth in the Summary Compensation Table above. Mr. French's annual base salary as of December 31, 2019 was \$412,000. The agreement also provides for certain option awards, each of which has previously been granted and is described in more detail above in the chart entitled "Outstanding Equity Awards as of December 31, 2019." If Mr. French's employment is terminated without cause (as defined in the agreement) or he resigns due to a significant reduction in duties, position or responsibilities, a 10% reduction in salary or a forced relocation more than 30 miles, then, subject to executing a release of claims and complying with 12-month non-solicit and non-compete covenants, Mr. French will receive 12 months of salary continuation and COBRA premium reimbursements. If the termination occurs within one month prior to or 12 months following a change of control (as defined in the agreement), any stock options then held by him will become fully vested and exercisable (except for certain designated options that are structured to vest only upon a change in control that represents an enterprise value of \$500 million).

### ***Offer Letter with Dr. Sung***

We entered into an offer letter with Dr. Sung in March 2019. The letter provides for an initial base salary of \$300,000 and target bonus of 25% of base salary. The letter also provides for certain option awards, each of which has previously been granted and is described in more detail above in the chart entitled "Outstanding Equity Awards as of December 31, 2019."

### ***Offer Letter with Mr. Rose***

We entered into an offer letter with Mr. Rose in December 2014. The letter provides for an initial base salary of \$240,000 and target bonus of 25% of base salary. Mr. Rose's annual base salary as of December 31, 2019 was \$272,600. The letter also provides for certain option awards, each of which has previously been granted and is described in more detail above in the chart entitled "Outstanding Equity Awards as of December 31, 2019."

## **Annual Bonus Plan**

Our named executive officers participate in our Annual Bonus Plan for Non-Sales Employees, pursuant to which a bonus payment may be earned based on the extent to which annual performance goals set by the Compensation Committee or the Board of Directors are met. Bonuses are paid during the first quarter of the year following the performance year. Annual bonus amounts paid with respect to 2019 are set forth in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table.

## **Employee Benefit Plans**

Our named executive officers participate in our health and welfare plans on the same basis as other employees.

Our named executive officers are also eligible to participate in our 401(k) plan on the same basis as other employees. Eligible employees are able to defer compensation pursuant to the terms of the 401(k) plan up to certain limits imposed by the Code. We have the ability to make matching and discretionary contributions to the 401(k) plan but have not done so to date. Employees are immediately and fully vested in their own contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code.



## **Pension Benefits**

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during 2019.

## **Nonqualified Deferred Compensation**

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during 2019.

## **Equity Incentive Plans**

### ***2020 Equity Incentive Plan***

We expect that our board of directors will adopt, and our stockholders will approve prior to the closing of this offering, our 2020 Equity Incentive Plan (2020 Plan). Our 2020 Plan will become effective on the date of the underwriting agreement related to this offering. The 2020 Plan came into existence upon its adoption by our board of directors, but no grants will be made under the 2020 Plan prior to its effectiveness. Once the 2020 Plan is effective, no further grants will be made under the 2010 Plan.

**Awards.** Our 2020 Plan provides for the grant of incentive stock options (ISOs) within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (Code) to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

**Authorized Shares.** Initially, the maximum number of shares of our common stock that may be issued under our 2020 Plan after it becomes effective will not exceed \_\_\_\_\_ shares of our common stock. In addition, the number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2021 through January 1, 2030, in an amount equal to (i) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on December 31 of the fiscal year before the date of each automatic increase or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2020 Plan is \_\_\_\_\_ shares.

Shares subject to awards granted under our 2020 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares do not reduce the number of shares available for issuance under our 2020 Plan. Shares withheld under an award to satisfy the exercise, strike or purchase price of an award or to satisfy a tax withholding obligation do not reduce the number of shares available for issuance under our 2020 Plan. If any shares of our common stock issued pursuant to an award are forfeited back to or repurchased or reacquired by us (1) because of a failure to meet a contingency or condition required for the vesting of such shares, (2) to satisfy the exercise, strike or purchase price of an award or (3) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2020 Plan. Any shares previously issued which are reacquired in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of an award will again become available for issuance under the 2020 Plan.

**Plan Administration.** Our board of directors, or a duly authorized committee of our board of directors, will administer our 2020 Plan and is referred to as the “plan administrator” herein. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified awards and (2) determine the number of shares subject to such awards. Under our 2020 Plan, our board of directors has the authority to determine award recipients, grant dates, the numbers and types of awards to be granted, the applicable fair market value, and the provisions of each award, including the period of exercisability and the vesting schedule applicable to an award.

*Stock Options.* ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2020 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2020 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2020 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient approved by the plan administrator, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO or (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

*Tax Limitations on ISOs.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

*Restricted Stock Unit Awards.* Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient approved by the plan administrator, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

*Restricted Stock Awards.* Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

*Stock Appreciation Rights.* Stock appreciation rights are granted under stock appreciation right agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2020 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may be settled in cash or shares of common stock or in any other form of payment as determined by the Board and specified in the stock appreciation right agreement.

The plan administrator determines the term of stock appreciation rights granted under the 2020 Plan, up to a maximum of ten years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

*Performance Awards.* The 2020 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the board of directors at the time the performance award is granted, the board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any portion of our business which is divested achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

*Other Equity Awards.* The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award (or cash equivalent) and all other terms and conditions of such awards.

*Non-Employee Director Compensation Limit.* The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed \$            in total value; provided that such amount will increase to            for the first year for newly appointed or elected non-employee directors.

*Changes to Capital Structure.* In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2020 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued on the exercise of ISOs, and (4) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding awards.

*Corporate Transactions.* The following applies to awards granted under the 2020 Plan in the event of a corporate transaction (as defined in the 2020 Plan), unless otherwise provided in a participant's award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction, any awards outstanding under the 2020 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such awards, then (i) with respect to any such awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event an award will terminate if not exercised prior to the effective time of a corporate transaction, the plan administrator may provide, in its sole discretion, that the holder of such award may not exercise such award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of common stock.

*Change in Control.* Awards granted under the 2020 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the 2020 Plan) as may be provided in the applicable award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

*Plan Amendment or Termination.* Our board of directors has the authority to amend, suspend or terminate our 2020 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2020 Plan. No awards may be granted under our 2020 Plan while it is suspended or after it is terminated.

### **2010 Equity Incentive Plan**

Our Amended and Restated 2010 Stock Plan (2010 Plan) was adopted by our board of directors and approved by our stockholders in February 2010, and was most recently amended on October 29, 2019. Our 2010 Plan permits the grant of incentive stock options within the meaning of Code Section 422 to our employees and to any of our parent or subsidiary corporation's employees, and nonstatutory stock options and restricted stock purchase rights to our employees, directors, and consultants and employees and consultants of any parent, subsidiary or affiliate of ours. Options to purchase the Company's common stock may be granted at a price not less than 100% of the fair market

value in the case of ISO or NSO, except for an employee or nonemployee with options who owns more than 10% of the voting power of all classes of stock of the Company in which case the exercise price shall be no less than 110% of the fair market value per share on the grant date. Our 2010 Plan will be terminated prior to the completion of this offering, and thereafter we will not grant any additional awards under our 2010 Plan. However, our 2010 Plan will continue to govern the terms and conditions of the outstanding awards previously granted thereunder.

*Share Reserve* . As of December 31, 2019, options to purchase 32,793,421 shares of our common stock were outstanding with a weighted-average exercise price of \$0.17 per share, and 776,032 shares of our common stock remained available for future awards under our 2010 Plan.

*Administration*. Our board of directors or a committee delegated by our board of directors administers our 2010 Plan. Subject to the terms of our 2010 Plan, the administrator has the power to, among other things, determine who will be granted awards, to determine the specific terms and conditions of each award (including the number of shares subject to the award and when the award will vest and, as applicable, become exercisable), to accelerate the time(s) at which an award may vest or be exercised, and to construe and interpret the 2010 Plan and awards granted thereunder.

*Capital Structure Changes*. In the event of certain changes in our capital structure, such as a stock split or recapitalization, appropriate and proportionate adjustments will be made to the number of shares reserved for issuance under our 2010 Plan; and the number of shares and price per share, if applicable, of all outstanding awards under our 2010 Plan.

*Corporate Transaction*. Our 2010 Plan provides that upon a corporate transaction, awards will be assumed or substituted in the transaction. If the surviving or acquiring corporation does not assume awards, they will terminate prior to the transaction, unless otherwise expressly provided in an individual award agreement or in any other written agreement with a participant. Under the 2010 Plan, a corporate transaction is generally the consummation of (1) a sale of all or substantially all of our assets or (2) our merger, consolidation or capital reorganization with or into another corporation (including a change of control, as described below).

*Change of Control*. Unless otherwise expressly provided in an individual award agreement or in any other written agreement with a participant, in the event of a change of control, if a participant who holds an outstanding award that is assumed or substituted by a successor corporation in the change of control, or holds restricted stock issued upon exercise of an outstanding option or stock purchase right, is involuntarily terminated (as defined in the 2010 Plan) by the successor corporation at, or within three months following, the closing of such transaction, then any such assumed or substituted awards will accelerate and become exercisable as to the number of shares that would otherwise have vested and been exercisable as of the date 30 days from the date of termination, and any repurchase right applicable to any shares will lapse as to the number of shares as to which the repurchase right would otherwise have lapsed as of the date 30 days from the date of termination. Under the 2010 Plan, a change of control is generally (1) a sale of all or substantially all of our assets or (2) our merger or consolidation with or into another corporation, other than a merger or consolidation in which the stockholders holding more than 50% of our shares immediately before the transaction own more than 50% of the voting power following the merger or consolidation.

*Amendment and Termination*. Our board of directors may amend, suspend or terminate our 2010 Plan at any time, subject to stockholder approval where such approval is required by applicable law. Our board of directors also may amend any outstanding award. However, no amendment to our 2010 Plan or an award granted thereunder may impair a participant's rights under an award without his or her written consent. As discussed above, we will terminate our 2010 Plan prior to the completion of this offering and no new awards will be granted thereunder following such termination.

#### **2020 Employee Stock Purchase Plan**

We expect that our board of directors will adopt, and our stockholders will approve prior to the closing of this offering, our 2020 Employee Stock Purchase Plan (2020 ESPP). The ESPP will become effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of the ESPP is to

secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment because of deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

*Share Reserve.* Following this offering, the ESPP authorizes the issuance of \_\_\_\_\_ shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2021 through January 1, 2030, by the lesser of (1) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on the last day of the fiscal year before the date of the automatic increase, and (2) \_\_\_\_\_ shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

*Administration.* Our board of directors administers the ESPP and may delegate its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of our common stock on the first date of an offering or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

*Limitations.* Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (1) being customarily employed for more than 20 hours per week, (2) being customarily employed for more than five months per calendar year or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

*Changes to Capital Structure.* In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to: (1) the class(es) and maximum number of shares reserved under the ESPP, (2) the class(es) and maximum number of shares by which the share reserve may increase automatically each year, (3) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights, and (4) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

*Corporate Transactions.* In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring

entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under the ESPP, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

*ESPP Amendment or Termination.* Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

### **Limitations on Liability and Indemnification Matters**

Upon the closing of this offering, our certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit. Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our certificate of incorporation will authorize us to indemnify our directors, officers, employees, and other agents to the fullest extent permitted by Delaware law. Our bylaws will provide that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our bylaws will also provide that, upon satisfaction of certain conditions, we will advance expenses incurred by a director or executive officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any executive officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers, and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines, and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these certificate of incorporation and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and executive officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and executive officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors, executive officers or employees for which indemnification has been sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers or persons controlling us, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### **Rule 10b5-1 Sales Plans**

Our directors and executive officers may adopt written plans that are intended to comply with Rule 10b5-1 under the Exchange Act, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or executive officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to the expiration of the period ending on, and including, the 180th day after the date of this prospectus, the sale of any shares under such plan would be subject to the lock-up agreement that the director or executive officer has entered into with the underwriters.



## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2016 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our then directors, executive officers or holders of more than 5% of any class of our capital stock at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described in “Executive Compensation” and “Management—Non-Employee Director Compensation.”

### Series F-1 Preferred Stock Financing

In May 2016, we issued and sold 15,151,515 shares of our Series F-1 preferred stock to Boston Scientific Corporation at a price of \$1.32 per share for aggregate gross proceeds of approximately \$20.0 million. In January 2017, we issued and sold 7,575,757 shares of our Series F-1 preferred stock to Boston Scientific Corporation at a price of \$1.32 per share for aggregate gross proceeds of approximately \$10.0 million. Each share of Series F-1 preferred stock will automatically convert into one share of our common stock upon the completion of this offering.

### Series G-1 Preferred Stock Financing

In April 2019, we issued and sold an aggregate of 49,342,376 shares of our Series G-1 preferred stock at a price of \$1.32 per share for aggregate gross proceeds of \$65.1 million, including the conversion of \$25.1 million of outstanding indebtedness under the Second Lien Loan and Security Agreement with BSC (BSC Agreement). Each share of Series G-1 preferred stock will automatically convert into one share of our common stock upon the completion of this offering. The following table summarizes the participation in the foregoing transactions by our directors, executive officers and holders of more than 5% of any class of our capital stock as of the date of such transactions:

Related Party	Shares of Series G-1 Preferred Stock	Aggregate Purchase Price
Entities affiliated with Ally Bridge Group	11,363,636	\$ 15,000,000
Entities affiliated with LVP Life Science Ventures III, L.P.	2,289,908	\$ 3,022,679
Montreux Growth Partners II, L.P.	2,263,453	\$ 2,987,758
Boston Scientific Corporation	20,819,097	\$ 27,481,213

### Loan and Security Agreement with BSC

In May 2017, we entered into the BSC Agreement. For more information regarding this agreement, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources; Plan of Operation.”

### Investor Rights, Voting and Co-Sale Agreements

In connection with our preferred stock financings, we entered into investor rights, voting, and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights, and rights of first refusal, among other things, with certain holders of our preferred stock and certain holders of our common stock, including entities affiliated with Montreux Equity Partners, an entity affiliated with Dr. Matly, entities affiliated with De Novo Ventures, an entity affiliated with Mr. Ferrari, entities affiliated with Latterell Venture Partners, an entity affiliated with Mr. Salmon, entities affiliated with HealthCap V L.P., an entity affiliated with Mr. Lindstrand, entities affiliated with KPCB Holdings, Inc., an entity affiliated with Mr. Mead, and entities affiliated with Ally Bridge Group, an entity affiliated with Mr. Chon. These stockholder agreements will terminate upon the closing of this offering, except for the registration rights granted under our investor rights agreement, as more fully described in “Description of Capital Stock—Registration Rights.”

### **Employment Agreements; Offer Letter Agreements**

We have entered into offer letter agreements with certain of our executive officers. For more information regarding these agreements with our named executive officers, see “Executive Compensation—Employment, Severance, and Change in Control Agreements.”

### **Stock Option Grants to Directors and Executive Officers**

We have granted stock options to certain of our directors and executive officers. For more information regarding the stock options and stock awards granted to our directors and named executive officers, see “Executive Compensation” and “Management—Non-Employee Director Compensation.”

### **Indemnification Agreements**

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined to be appropriate by the board. In addition, we have entered into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them to the fullest extent permitted by the Delaware General Corporation Law. For more information regarding these agreements, see the section titled “Executive Compensation—Limitations on Liability and Indemnification Matters.”

### **Related-Person Transaction Policy**

In connection with this offering, we intend to adopt a policy that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, will not be permitted to enter into a related-party transaction with us without the prior consent of our audit committee, or other independent members of our board of directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, principal stockholder or any of their immediate family members or affiliates, in which the amount involved exceeds \$120,000, must first be presented to our audit committee for review, consideration, and approval. In approving or rejecting any such proposal, our audit committee will consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, but not limited to, whether the transaction will be on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related-party’s interest in the transaction.

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to relationship or interest of the relevant director, officer or holder of 5% or more of any class of our voting securities in the agreement or transaction was disclosed to our board of directors. Our board of directors took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

## PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of December 31, 2019, as adjusted to reflect the sale of common stock offered by us in this offering, for:

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

The percentage ownership information shown in the table prior to this offering is based upon 196,835,746 shares of common stock outstanding as of December 31, 2019, after giving effect to the conversion of all outstanding shares of preferred stock into 175,832,872 shares of our common stock immediately prior to the closing of this offering. The percentage ownership information shown in the table after this offering is based upon shares outstanding, assuming the sale of shares of our common stock by us in the offering and no exercise of the underwriters' option to purchase additional shares of common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before February 29, 2020 which is 60 days after December 31, 2019. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o Pulmonx Corporation, 700 Chesapeake Drive, Redwood City, California, 94063.

Name of Beneficial Owner	Number of Shares Beneficially Owned Before this Offering	Percentage of Shares Beneficially Owned	
		Before this Offering	After this Offering
<b>Principal Stockholders</b>			
Boston Scientific Corporation <sup>(1)</sup>	59,881,087	30.42%	%
KPCB Holdings, Inc. <sup>(2)</sup>	15,241,102	7.70	
Entities Affiliated with LVP III Associates, L.P. <sup>(3)</sup>	14,505,952	7.37	
Entities Affiliated with Montreux Equity Partners <sup>(4)</sup>	14,299,438	7.26	
De Novo Ventures III Liquidating Trust <sup>(5)</sup>	12,323,243	6.26	
Entities Affiliated with Ally Bridge Group <sup>(6)</sup>	11,363,636	5.77	
Entities Affiliated with HealthCap V L.P. <sup>(7)</sup>	11,337,307	5.74	
<b>Directors and Named Executive Officers</b>			
Glendon E. French <sup>(8)</sup>	12,784,560	6.11	
Derrick Sung, Ph.D. <sup>(9)</sup>	2,286,595	1.16	
Geoffrey Beran Rose <sup>(10)</sup>	2,329,093	1.17	
Charles Chon	—	*	
Richard Ferrari	—	*	
Daniel Florin <sup>(11)</sup>	60,000	*	
Staffan Lindstrand	—	*	
Dana G. Mead, Jr. <sup>(12)</sup>	60,000	*	
Michael Matly, M.D. <sup>(13)</sup>	2,263,453	1.15	
Rodney Perkins, M.D. <sup>(14)</sup>	3,267,031	1.65	
Steven Salmon	—	*	
Oern Stuge, M.D. <sup>(15)</sup>	900,035	*	
All directors and executive officers as a group (12 persons) <sup>(16)</sup>	23,950,767	11.21	

\* Represents beneficial ownership of less than 1%

(1) The principal business address for Boston Scientific Corporation is 300 Boston Scientific Way, Marlborough, MA 01752-1234.

(2) Consists of (a) 10,772,301 shares of our Series C-1 Preferred Stock held by Kleiner Perkins Caufield & Byers XIII, LLC (“KPCB XIII”) and 778,526 shares held by individuals and entities associated with Kleiner Perkins Caufield & Byers (“KPCB”), (b) 1,568,849 shares of our Series D-1 Preferred Stock held by KPCB XIII and 113,382 shares held by individuals and entities associated with KPCB (c) 815,796 shares of our Series E-1 Preferred Stock held by KPCB XIII and 58,958 shares held by individuals and entities associated with KPCB and (d) warrants to purchase 1,056,906 shares of our Series C-1 Preferred Stock held by KPCB XIII and warrants to purchase 76,384 shares of our Series C-1 Preferred Stock held by individuals and entities associated with KPCB. All shares are held for convenience in the name of “KPCB Holdings, Inc., as nominee” for the accounts of such individuals and entities. The managing member of KPCB XIII is KPCB XIII Associates, LLC (“KPCB XIII Associates”). L. John Doerr, Raymond J. Lane, Theodore E. Schlein and Brook H. Byers, the managing members of KPCB XIII Associates, exercise shared voting and dispositive control over the shares held by KPCB XIII. The principal business address for all entities and individuals affiliated with KPCB is c/o Kleiner Perkins Caufield & Byers, LLC, 2750 Sand Hill Road, Menlo Park, CA 94025.

(3) Consists of (a) 674,695 shares held by LVP III Associates, L.P., (b) 337,344 shares held by LVP III Partners, L.P. and (c) 13,493,913 shares held by LVP Life Science Ventures III, L.P. LVP GP III, LLC is the general partner of LVP III Associates, L.P., LVP III Partners, L.P. and LVP Life Science Ventures III, L.P. Patrick Latterell, Stephen Salmon and James Woody, the members of LVP GP III, LLC, share voting and

investment power with respect to these shares. The principal business address for all entities and individuals affiliated with Latterell Venture Partners is 2603 Camino Ramon, Suite 200, San Ramon, CA 94583.

- (4) Consists of (a) 5,571,410 shares held by Montreux Equity Partners II SBIC, L.P. (“Montreux Equity II”), (b) 6,402,459 shares held by Montreux Equity Partners III SBIC, L.P. (“Montreux Equity III”), (c) 2,263,453 shares held by Montreux Growth Partners II, L.P. (“Montreux Growth”), (d) warrants to purchase 28,693 shares held by Montreux Equity II and (e) warrants to purchase 33,423 shares held by Montreux Equity III. Montreux Equity Management II SBIC, LLC is the general partner of Montreux Equity II, Montreux Equity Management III SBIC, LLC is the general partner of Montreux Equity III and Montreux Growth Management II, LLC is the general partner of Montreux Growth. Daniel K. Turner III is the managing member of Montreux Equity Management II SBIC, LLC and Montreux Equity Management III SBIC, LLC. Daniel K. Turner III and Dr. Michael Matly are the managing members of Montreux Growth Management II, LLC. The principal business address for all entities and individuals affiliated with Montreux Equity Partners is Four Embarcadero Center, Suite 3720, San Francisco, CA 94111.
- (5) The trustees of the De Novo Ventures III Liquidating Trust (“De Novo”) are Fred Dotzler, Richard Ferrari, Joseph Mandato and Jay Watkins. These trustees exercise shared voting and dispositive control over the shares held by De Novo. The address for De Novo is PO Box 2160, Saratoga, California 95070.
- (6) Consists of (a) 3,030,303 shares held by ABG YY Limited (“ABG YY”) and (b) 8,333,333 shares held by ABG-Pulmonx Limited (“ABG Pulmonx”). ABG Fund III exercises voting and dispositive control of all shares held by ABG Pulmonx. ABG Innovation Capital Partners III GP Limited is the general partner of ABG Innovation Capital Partners III GP, L.P., which is the general partner of ABG Fund III. Mr. Fan Yu (Frank) is the sole shareholder and sole director of ABG Innovation Capital Partners III GP Limited. The board of directors of ABG Management Ltd., consisting of Mr. Fan Yu (Frank) and Mr. Chee On Pang (Andrew), exercises voting and dispositive control of all shares held by ABG YY. Mr. Charles Chon is a partner and managing director of Ally Bridge Group. The principal business address for all entities and individuals affiliated with Ally Bridge Group is Unit 3002-3004, 30/F., Gloucester Tower, The Landmark, 15 Queen’s Road Central, Hong Kong; ABG YY Limited: 27/F, No. 238 Des Voeux Road Central, Hong Kong.
- (7) Consists of (a) 10,402,090 shares held by HealthCap V, L.P. (“HCLP”), (b) 158,406 shares held by OFCO Club V (“OFCO”), (c) warrants to purchase 765,159 shares held by HCLP and (d) warrants to purchase 11,652 shares held by OFCO. HealthCap V GP SA (“HCSA”) is the sole general partner of HCLP. HCSA has voting and dispositive power over the shares held by HCLP. Björn Odlander, Peder Fredrikson, Staffan Lindstrand, Anki Forsberg, Per Samuelsson, Johan Christenson, Jacob Gunterberg, Mårten Steen, Per-Olof Eriksson, Carl-Johan Dalsgaard and Eugen Steiner, the members of HCSA, may be deemed to possess voting and dispositive power over the shares held by HCLP and may be deemed to have indirect beneficial ownership of the shares held by such entities. The principal business address for HCSA is c/o HealthCap V GP SA, 18, Avenue d’Ouchy, 1006 Lausanne, Switzerland. OFP V Advisor AB, (“OFP V AB”) is a member of OFCO and has voting and dispositive control over the shares held by OFCO. Björn Odlander, Per Olof Eriksson, and Ann Christine Forsberg are members of the Board of OFP V AB. Further, Björn Odlander, Peder Fredrikson, Staffan Lindstrand, Ann Christine Forsberg, Per Samuelsson, Johan Christenson, Jacob Gunterberg, Per-Olof Eriksson, Carl-Johan Dalsgaard and Eugen Steiner are directly or indirectly members of OFP V AB and may be deemed to possess voting and dispositive control over the shares held by OFCO and may be deemed to have indirect beneficial ownership of the shares held by OFCO. The principal address for OFP and individuals affiliated with HealthCap is Engelbrektsplan 1, 114 34 Stockholm, Sweden.
- (8) Represents (a) 285,714 shares held by Glendon E. French III Children’s Irrevocable Trust dated November 17, 1998, (b) 12,498,846 shares issuable pursuant to immediately exercisable options, including 9,302,450 shares issuable following exercise of such options that are scheduled to vest within 60 days of December 31, 2019.
- (9) Represents (a) 1,524,396 shares held by Mr. Sung, all of which are subject to a right of repurchase by us as of February 29, 2020, 60 days after December 31, 2019 and (b) 762,199 shares issuable pursuant to immediately exercisable options, all of which are currently unvested and exercisable and will begin vesting monthly upon the closing of this offering.
- (10) Represents (a) 575,634 shares held by Mr. Rose and (b) 1,753,459 shares issuable pursuant to immediately exercisable options, including 1,212,625 shares issuable following exercise of such options that are scheduled to vest within 60 days of December 31, 2019.
- (11) Represents 60,000 shares issuable pursuant to an immediately exercisable option, including 20,000 shares issuable following exercise of such option that are scheduled to vest within 60 days of December 31, 2019.
- (12) Represents 60,000 shares issuable pursuant to an immediately exercisable option, including 20,000 shares issuable following exercise of such option that are scheduled to vest within 60 days of December 31, 2019.
- (13) Consists of 2,263,453 shares held by Montreux Growth Partners II, L.P. (“Montreux Growth”). Montreux Growth Management II, LLC is the general partner of Montreux Growth. Daniel K. Turner III and Dr. Michael Matly are the managing members of Montreux Growth Management II, LLC. The principal business address for all entities and individuals affiliated with Montreux Equity Partners is Four Embarcadero Center, Suite 3720, San Francisco, CA 94111.
- (14) Represents (a) 100,000 shares held by Rodney C. Perkins, as Trustee of the Perkins Family Revocable Trust dated February 28, 1986, (b) 2,202,031 shares held by Mr. Perkins and (c) 965,000 shares issuable pursuant to immediately exercisable options, all of which are scheduled to vest within 60 days of December 31, 2019.

- (15) Represents (a) 262,541 shares held by Mr. Stuge and (b) 637,494 shares issuable pursuant to immediately exercisable options, all of which are scheduled to vest within 60 days of December 31, 2019.
- (16) Includes (a) 7,213,769 shares and (b) 16,736,998 shares issuable pursuant to immediately exercisable options, including 12,157,569 shares issuable following exercise of such options that are scheduled to vest within 60 days of December 31, 2019.

## DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock, certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws, as each will be in effect upon the completion of this offering, and certain provisions of Delaware law are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part. We refer in this section to our amended and restated certificate of incorporation and amended and restated bylaws that we intend to adopt in connection with this offering as our certificate of incorporation and bylaws, respectively.

### **General**

Upon the completion of this offering, our amended and restated certificate of incorporation will authorize us to issue up to \_\_\_\_\_ shares of our common stock, \$0.001 per value per share. In addition, our amended and restated certificate of incorporation will authorize \_\_\_\_\_ shares of undesignated preferred stock, \$0.001 par value per share, the rights, preferences, and privileges of which may be designated from time to time by our board of directors.

As of December 31, 2019, we had 21,002,874 shares of common stock held by 270 stockholders of record and 175,832,872 shares of preferred stock outstanding. After giving effect to the conversion of all outstanding shares of preferred stock into shares of common stock immediately upon the closing of this offering there would have been 196,835,746 shares of common stock outstanding on December 31, 2019, held by 328 stockholders of record. As of December 31, 2019, we had outstanding warrants to purchase 2,152,939 shares of preferred stock with an exercise price of \$1.057 per share, which warrants will expire on the earlier of (i) February 9, 2020 or (ii) the closing of this offering. As of December 31, 2019, we also had outstanding options to acquire 32,793,421 shares of common stock.

### **Common Stock**

#### ***Dividend and Distribution Rights***

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

#### ***Voting Rights***

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

#### ***No Preemptive or Similar Rights***

Our common stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions. The rights, preferences, and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of our preferred stock that we may designate and issue in the future.

#### ***Liquidation Rights***

In the event of our liquidation, dissolution or winding-up, upon the completion of the distributions required with respect to any series of preferred stock that may then be outstanding, or remaining assets legally available for distribution to stockholders shall be distributed on an equal priority, pro rata basis to the holders of common stock.

## **Preferred Stock**

All currently outstanding shares of our preferred stock will be converted to common stock immediately upon the closing of this offering.

Following the completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to \_\_\_\_\_ shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences, and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common 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 and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in control and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of our common stock until our board of directors determines the specific rights attached to that preferred stock.

We have no present plans to issue any shares of preferred stock.

## **Options**

As of December 31, 2019, options to purchase an aggregate of 32,793,421 shares of our common stock were outstanding under our 2010 Plan at a weighted-average exercise price of \$0.17 per share. For additional information regarding the terms of our 2010 Plan, see “Executive Compensation—Employee Benefit Plans—2010 Equity Incentive Plan.”

## **Warrants**

As of December 31, 2019, we had warrants to purchase an aggregate of 2,152,939 shares of our Series C-1 preferred stock outstanding with an exercise price of \$1.057 per share. These warrants expire on the earlier of (a) February 9, 2020, (b) the sale, conveyance or disposal of all or substantially all of our property or business, or our merger with or into or consolidation with any other corporation, limited liability company or other entity, and (c) the closing of this offering.

## **Registration Rights**

After the completion of this offering, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon conversion of our preferred stock in connection with this offering, will be entitled to certain rights with respect to registration of such shares under the Securities Act pursuant to the terms of an investor rights agreement. These shares are collectively referred to herein as registrable securities.

The investor rights agreement provides the holders of registrable securities with demand, piggyback and S-3 registration rights as described more fully below. As of December 31, 2019, after giving effect to the conversion of all outstanding shares of preferred stock into shares of our common stock in connection with the completion of this offering, there would have been an aggregate of 184,166,734 registrable securities that were entitled to these demand registration rights, an aggregate of 184,166,734 registrable securities that were entitled to these piggyback registration rights, and an aggregate of 184,166,734 registrable securities that were entitled to these S-3 registration rights. The number of registrable securities that were entitled to the piggyback registration rights and the S-3



registration rights as of December 31, 2019 does not include shares of common stock issuable upon exercise of warrants, which were also entitled to such piggyback registration rights and the S-3 registration rights.

### ***Demand Registration Rights***

At any time beginning six months after the effective date of the registration statement of which this prospectus forms a part, the holders of at least a majority of the registrable securities then outstanding have the right to make up to two demands that we file a registration statement under the Securities Act covering at least 25% of the registrable securities then outstanding, subject to specified exceptions.

### ***Piggyback Registration Rights***

If we register any securities for public sale, the holders of our registrable securities then outstanding will each be entitled to notice of the registration and will have the right to include their shares in the registration statement.

The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement, but not below 20% of the total number of securities included in such registration.

### ***Registration on Form S-3***

If we are eligible to file a registration statement on Form S-3, the holders of at least 25% our registrable securities have the right to demand that we file registration statements on Form S-3; provided, that the aggregate amount of securities to be sold under the registration statement is at least \$1.0 million. We are not obligated to effect a demand for registration on Form S-3 by holders of our registrable securities more than once during any 12-month period. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

### ***Expenses of Registration***

We will pay all expenses relating to any demand, piggyback, or Form S-3 registration, other than underwriting discounts and commissions, subject to specified conditions and limitations.

### ***Termination of Registration Rights***

The registration rights will terminate three years following the completion of this offering and, with respect to any particular stockholder, when such stockholder is able to sell all of its shares during a 90-day period pursuant to Rule 144 under the Securities Act or another similar exemption.

### ***Anti-Takeover Provisions***

#### ***Anti-Takeover Statute***

We are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a publicly held 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, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion 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 (1) by 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 the 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 $\frac{2}{3}$ % of the outstanding voting stock that is not owned by the interested stockholder.

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

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge, or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- 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;
- subject to certain exceptions, 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 loans, advances, guarantees, pledges, or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity (other than the corporation and any direct or indirect majority-owned subsidiary of the corporation) 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.

#### ***Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation and Bylaws to be in Effect Upon the Completion of this Offering***

Our certificate of incorporation will provide for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of our common stock outstanding will be able to elect all of our directors. Our certificate of incorporation and bylaws will also provide that directors may be removed by the stockholders only for cause upon the vote of 66 $\frac{2}{3}$ % or more of our outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of our board of directors, and vacancies and newly created directorships on our board of directors may, except as otherwise required by law or determined by our board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Our certificate of incorporation and bylaws will also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. Our bylaws will also provide that only our chairman of the board, chief executive officer or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our bylaws will also provide that stockholders seeking to present proposals before our annual meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and, subject to applicable law, will specify requirements as to the form and content of a stockholder’s notice.

Our certificate of incorporation and bylaws will provide that the stockholders cannot amend many of the provisions described above except by a vote of 66⅔% or more of our outstanding common stock.

The combination of these provisions will 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 could 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 our control.

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 coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

### **Choice of Forum**

Our amended and restated certificate of incorporation to be in effect upon the completion of this offering will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by any of our directors, officers, employees, or stockholders to us or our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation to be in effect upon the completion of this offering will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. See “Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—Our amended and restated certificate of incorporation that will be in effect at the closing of this offering will provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States will be the exclusive forums 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”

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is \_\_\_\_\_ . The transfer agent’s address is \_\_\_\_\_ and the telephone number is \_\_\_\_\_ .

### **Listing**

We have applied to list our common stock on the Nasdaq Global Market under the trading symbol “PMNX.”

## SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, no public market for our common stock existed, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market could adversely affect prevailing market prices of our common stock from time to time and could impair our ability to raise equity capital in the future. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

Based upon the number of shares outstanding as of December 31, 2019, upon the closing of this offering, we will have outstanding an aggregate of \_\_\_\_\_ shares of common stock (or \_\_\_\_\_ shares if the underwriters exercise in full their option to purchase additional shares of our common stock). This includes shares of common stock that we are selling in this offering, which shares may be resold in the public market immediately following this offering, and assumes no exercise of outstanding options or warrants, after giving effect to the conversion of all outstanding shares of our preferred stock into 175,832,872 shares of common stock immediately upon the closing of this offering. All of the shares sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, unless held by our affiliates, as that term is defined under Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, or subject to lock-up agreements. The remaining shares of common stock outstanding upon the closing of this offering are restricted securities as defined in Rule 144. Restricted securities may be sold in the U.S. public market only if registered under the Securities Act or if they qualify for an exemption from registration, including by reason of Rule 144 or Rule 701 under the Securities Act, which rules are summarized below. Subject to the lock-up arrangements described below and the provisions of Rule 144, these restricted securities will be available for sale in the public market after the date of this prospectus.

As of December 31, 2019, of the 32,793,421 shares of common stock issuable upon exercise of options outstanding, approximately 32,793,421 shares will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act. All of these restricted securities will be subject to the 180-day lock-up period described below. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which are summarized below, or any other exemption and, if subject to lock-up agreements, may only be sold after the expiration of the 180-day lock-up period.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our 2020 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act, or an exemption from registration, including Rule 144 and Rule 701.

### **Rule 144**

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of us who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

## ***Non-Affiliates***

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to resell an unlimited number of restricted securities effective immediately upon the completion of this offering without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting. Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

## ***Affiliates***

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. Sales of restricted or unrestricted shares of our common stock by affiliates are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell in “broker’s transactions” or certain “reckless principal transactions” or to market makers, within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately                      shares immediately after the completion of this offering based on the number of shares outstanding as of December 31, 2019; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission (SEC) and Nasdaq Global Market concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

## **Rule 701**

In general, under Rule 701 a person who purchased shares of our common stock pursuant to a written compensatory stock or option plan or contract before the effective date of a registration statement under the Securities Act and who is not deemed to have been one of our affiliates during the immediately preceding 90 days may sell these shares in reliance upon Rule 144, but without being required to comply with the notice, manner of sale or public information requirements or volume limitation provisions of Rule 144. Rule 701 also permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under “Underwriting” included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

### **Form S-8 Registration Statements**

As soon as practicable after the completion of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the shares of our common stock that are issuable pursuant to our equity incentive plans, including pursuant to outstanding options. See “Executive Compensation—Employee Benefit Plans” for a description of our equity incentive plans. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

### **Lock-Up Agreements**

In connection with this offering, we, our directors and officers, and substantially all of our other existing security holders have agreed, subject to certain limited exceptions, not to offer, sell or transfer any of our common stock, stock options or other securities convertible into, exchangeable for, or exercisable for, our common stock for 180 days after the date of this prospectus without the prior written consent of BofA Securities, Inc. and Morgan Stanley & Co. LLC on behalf of the underwriters. See “Underwriting” for a more complete description of the lock-up agreements that we, our directors, executive officers, and substantially all of our other existing security holders will enter into in connection with this offering.

Any determination to release shares subject to the lock-up agreements would be based on a number of factors at the time of determination, including but not necessarily limited to the market price of the common stock, the liquidity of the trading market for the common stock, general market conditions, the number of shares proposed to be sold, contractual obligations to release certain shares subject to the lock-up agreements in the event any such shares are released, subject to certain specific limitations and thresholds, and the timing, purpose, and terms of the proposed sale.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain of our security holders, including our investor rights agreement and agreements governing our equity awards, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

### **Registration Rights**

Upon the completion of this offering, the holders of 184,166,734 shares of our common stock, or their transferees, subject to any lock-up agreements they have entered into, will be entitled to specified rights with respect to the registration of the offer and sale of common stock issuable upon conversion of such shares of common stock under the Securities Act. Registration of the offer and sale of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See “Description of Capital Stock—Registration Rights” for additional information.

## MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common stock by “Non-U.S. Holders” (as defined below). This discussion is for general information purposes only and does not consider all aspects of U.S. federal income taxation that may be relevant to particular Non-U.S. Holders in light of their individual circumstances or to certain types of Non-U.S. Holders subject to special tax rules, including partnerships or other entities or arrangements treated as pass-through or disregarded entities for U.S. federal income tax purposes, banks, financial institutions or other financial services entities, broker-dealers, insurance companies, tax-exempt organizations, governmental organizations, pension plans, real estate investment trusts, controlled foreign corporations, passive foreign investment companies, regulated investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons who use or are required to use mark-to-market accounting, persons that hold more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, persons that are “qualified foreign pension funds” as defined in Section 897(1)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds, persons that hold our shares as part of a “straddle,” a “hedge,” a “conversion transaction,” “synthetic security,” integrated investment, or other risk reduction strategy, certain U.S. expatriates and former citizens or permanent residents of the United States, persons deemed to sell our common stock under the constructive sale provisions of the Code, persons who hold or receive shares of our common stock pursuant to the exercise of an employee stock option or otherwise as compensation, or investors in pass-through entities (or entities that are treated as disregarded entities for U.S. federal income tax purposes). In addition, this discussion does not address the potential application of the gift or estate tax, alternative minimum tax, Medicare contribution tax on net investment income, or any tax considerations that may apply to Non-U.S. Holders under state, local or non-U.S. tax laws, and any other U.S. federal tax laws. Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax considerations that may be relevant to them.

This discussion is based on the Code and applicable Treasury regulations promulgated thereunder (Treasury Regulations) rulings, administrative pronouncements, and judicial decisions that are issued and available as of the date of this registration statement, all of which are subject to change or differing interpretations at any time with possible retroactive effect. We have not sought, and will not seek, any ruling from the Internal Revenue Service (IRS) with respect to the tax consequences discussed herein, and there can be no assurance that the IRS will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained. This discussion is limited to a Non-U.S. Holder who will hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). For purposes of this discussion, the term “Non-U.S. Holder” means a beneficial owner of our common stock that is not a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes) and is not, for U.S. federal income tax purposes, any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation) created or organized in the United States or under the laws of the United States or of 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 if (1) a court within the United States can exercise primary supervision over the trust’s administration and one or more U.S. persons have the authority to control all of the trust’s substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of our common stock, the tax treatment of such partnership and a partner in such partnership generally will depend upon the status of the partner and the activities of the partnership. If you are a partner of a partnership holding our shares, you should consult your tax advisor regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

**THIS SUMMARY IS NOT INTENDED TO BE TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.**

### **Distributions on Our Common Stock**

In general, subject to the discussion below under the headings “Information Reporting and Backup Withholding” and “Foreign Accounts,” distributions, if any, paid on our common stock to a Non-U.S. Holder (to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles) will constitute dividends and be subject to U.S. withholding tax at a rate equal to 30% of the gross amount of the dividend, or a lower rate prescribed by an applicable income tax treaty, unless the dividends are effectively connected with a trade or business carried on by the Non-U.S. Holder within the United States. Any distribution not constituting a dividend (because such distribution exceeds our current and accumulated earnings and profits) will be treated first as reducing the Non-U.S. Holder’s basis in its shares of common stock, but not below zero, and to the extent it exceeds the Non-U.S. Holder’s basis, as capital gain from the sale or exchange of such stock (see “Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock” below).

A Non-U.S. Holder who claims the benefit of an applicable income tax treaty generally will be required to satisfy certain certification and other requirements prior to the distribution date. Such Non-U.S. Holders must generally provide us or our paying agent, as applicable, with a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or other appropriate form) claiming an exemption from or reduction in withholding under an applicable income tax treaty. Such certificate must be provided before the payment of dividends and must be updated periodically. If tax is withheld in an amount in excess of the amount applicable under an income tax treaty, a refund of the excess amount may generally be obtained by a Non-U.S. Holder 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 an applicable income tax treaty.

Dividends that are effectively connected with a Non-U.S. Holder’s conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base of the Non-U.S. Holder) generally will not be subject to U.S. federal withholding tax if the Non-U.S. Holder files the required forms, including IRS Form W-8ECI with us or our paying agent, as applicable, but instead generally will be subject to U.S. federal income tax on a net income basis at regular rates in the same manner as if the Non-U.S. Holder were a resident of the United States. A corporate Non-U.S. Holder that receives effectively connected dividends may be subject to an additional branch profits tax at a rate of 30%, or a lower rate prescribed by an applicable income tax treaty.

### **Gain on Sale, Exchange or Other Disposition of Our Common Stock**

In general, subject to the discussion below under the headings “Information Reporting and Backup Withholding” and “Foreign Accounts,” a Non-U.S. Holder will not be subject to U.S. federal income tax or withholding tax on any gain realized upon such holder’s sale, exchange or other disposition of shares of our common stock unless: (1) the gain is effectively connected with a trade or business carried on by the Non-U.S. Holder within the United States (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base of the Non-U.S. Holder); (2) the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or (3) we are or have been a “United States real property holding corporation” for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. Holder held our common stock, and, in the case where shares of our common stock are regularly traded on an established securities market, the Non-U.S. Holder owns, or is treated as owning, more than 5% of our common stock at any time during the foregoing period.



Net gain realized by a Non-U.S. Holder described in clause (1) above generally will be subject to U.S. federal income tax in the same manner as if the Non-U.S. Holder were a resident of the United States. Any gains of a corporate Non-U.S. Holder described in clause (1) above may also be subject to an additional “branch profits tax” at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty.

Gain realized by an individual Non-U.S. Holder described in clause (2) above will be subject to a flat 30% tax (or such lower rate as may be specified by an applicable income tax treaty), which gain may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States, provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

For purposes of clause (3) above, a corporation is a United States real property holding corporation (USRPHC) if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus any assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not, and we do not anticipate that we will become, a USRPHC. Even if we became a USRPHC, a Non-U.S. Holder would not be subject to U.S. federal income tax on a sale, exchange, or other taxable disposition of our common stock by reason of our status as an USRPHC so long as our common stock is regularly traded on an established securities market (within the meaning of the applicable Treasury Regulations) and such Non-U.S. Holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of our outstanding common stock at any time during the shorter of the five year period ending on the date of disposition and such holder’s holding period. However, no assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. If we are a USRPHC and our common stock is not regularly traded on an established securities market, such Non-U.S. Holder’s proceeds received on the disposition of shares will generally be subject to withholding at a rate of 15% and such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

### **Information Reporting and Backup Withholding**

Generally, we must report annually to the IRS and to each Non-U.S. Holder the amount of dividends paid, the name and address of the recipient, and the amount, if any, of tax withheld. These information reporting requirements apply even if withholding was not required because the dividends were effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States or withholding was reduced by an applicable income tax treaty. Under applicable income tax treaties or other agreements, the IRS may make its reports available to the tax authorities in the country in which a Non-U.S. Holder is resident or organized.

Dividends paid to a Non-U.S. Holder that is not an exempt recipient generally will be subject to backup withholding, currently at a rate of 24%, unless the Non-U.S. Holder certifies to the payor as to its foreign status, which certification may generally be made on an applicable IRS Form W-8. Notwithstanding the foregoing, backup withholding may apply if we have actual knowledge, or reason to know, that the Non-U.S. Holder is a U.S. person (as defined in the Code) that is not an exempt recipient.

Proceeds from the sale or other disposition of common stock by a Non-U.S. Holder effected by or through a U.S. office of a broker will generally be subject to information reporting and backup withholding, currently at a rate of 24%, unless the Non-U.S. Holder certifies to the withholding agent under penalties of perjury as to, among other things, its name, address, and status as a Non-U.S. Holder (which certification may generally be made on an applicable IRS Form W-8) or otherwise establishes an exemption. Payment of disposition proceeds effected outside the United States by or through a non-U.S. office of a non-U.S. broker generally will not be subject to information reporting or backup withholding if the payment is not received in the United States. Information reporting, but generally not backup withholding, will apply to such a payment if the broker has certain connections with the United States unless the broker has documentary evidence in its records that the beneficial owner thereof is a Non-U.S. Holder and specified conditions are met or an exemption is otherwise established.

Backup withholding is not an additional tax. Any amount withheld under the backup withholding rules from a payment to a Non-U.S. Holder that results in an overpayment of taxes generally will be refunded, or credited against the holder's U.S. federal income tax liability, if any, provided that the required information is timely furnished to the IRS.

### **Foreign Accounts**

Sections 1471 through 1474 of the Code regarding the Foreign Account Tax Compliance Act (commonly referred to as FATCA) generally impose a 30% withholding tax on dividends on, and, subject to the discussion of certain proposed Treasury Regulations below, gross proceeds from the sale or disposition of, our common stock if paid to a foreign entity unless (1) if the foreign entity is a "foreign financial institution," (as specifically defined by applicable rules) the foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (2) if the foreign entity is not a "foreign financial institution," the foreign entity identifies certain U.S. holders of debt or equity interests in such foreign entity, or (3) the foreign entity is otherwise exempt from FATCA. The U.S. Treasury recently released proposed Treasury Regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed Treasury Regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued.

An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a Non-U.S. Holder may be eligible for refunds or credits of the tax. Non-U.S. Holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

**EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT OR PROPOSED CHANGE IN APPLICABLE LAW.**

**UNDERWRITING**

BofA Securities, Inc. and Morgan Stanley & Co. 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 and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
Morgan Stanley & Co. LLC	
Stifel, Nicolaus & Company, Incorporated	
Wells Fargo Securities, LLC	
Canaccord Genuity LLC	
Total	

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 have agreed to indemnify the 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 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. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

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

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

## 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 \_\_\_\_\_ 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, our executive officers and directors and substantially all of our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Morgan Stanley & Co. LLC. 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 for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file a registration statement or make a confidential submission related to the common stock,
- enter into any swap or other agreement or transaction 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, or
- publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with 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. BofA Securities, Inc. and Morgan Stanley & Co. LLC in their 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.

## Nasdaq Listing

We expect the shares to be approved for listing on the Nasdaq Global Market, subject to notice of issuance, under the symbol "PMNX."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,

- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

### **Price Stabilization, Short Positions and Penalty Bids**

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.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

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 Nasdaq Global Market, 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 or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations 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 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 (Member State), no shares have been offered or will be offered pursuant to the initial offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares shall require the company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the company and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a relevant Member State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer 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 any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

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 (Order) 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 (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 (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 (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 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, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (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 (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, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (SFA)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, 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 or securities-based derivatives contracts (each term as defined in Section 2(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, 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; or
- (d) as specified in Section 276(7) of the SFA.

#### **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

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Palo Alto, California. Certain legal matters will be passed upon for the underwriters by Shearman & Sterling LLP, New York, New York. VLG Investments 1993 and VLG Investments 1994, each of which are entities in which certain partners of Cooley LLP are investors, beneficially own an aggregate 3,341 shares of our common stock.

## EXPERTS

The consolidated financial statements as of December 31, 2018 and for the year then ended included in this prospectus and in the registration statement, have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains explanatory paragraphs regarding the company's ability to continue as a going concern and change in accounting principle related to revenue recognition), appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND ADDITIONAL 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 being offered by this prospectus, which constitutes a part of the registration statement. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at [www.sec.gov](http://www.sec.gov).

Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements, and other information with the SEC. These reports, proxy statements, and other information will be available for inspection and copying at the website of the SEC referred to above. We also maintain a website at [www.pulmonx.com](http://www.pulmonx.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. **However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our common stock in this offering.**

**Pulmonx Corporation**  
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## Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders  
Pulmonx Corporation  
Redwood City, California

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Pulmonx Corporation (the “Company”) as of December 31, 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders’ deficit, and cash flows for the year then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has negative cash flows from operating activities, and a significant accumulated deficit, which raises substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for revenue in 2018 due to the adoption of Accounting Standards Codification 606, *Revenue from Contracts with Customers*. The Company adopted the new revenue standard using the full retrospective approach.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 audit 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 audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2011.

San Jose, California  
December 13, 2019

Pulmonx Corporation

Consolidated Balance Sheet

(in thousands, except share and per share amounts)

	December 31, 2018
<b>Assets</b>	
Current assets	
Cash and cash equivalents	\$ 4,124
Accounts receivable, net	2,950
Inventory	3,320
Prepaid expenses and other current assets	914
Total current assets	11,308
Property and equipment, net	375
Goodwill	2,333
Intangible assets, net	647
Other long-term assets	350
Total assets	15,013
<b>Liabilities, Convertible Preferred Stock and Stockholders' Deficit</b>	
Current liabilities	
Accounts payable	1,289
Accrued liabilities	5,876
Income taxes payable	48
Deferred revenue	139
Deferred rent	78
Derivative liability	642
Total current liabilities	8,072
Deferred tax liability	48
Deferred rent, net of current portion	67
Term loan	14,937
Convertible note payable to related party	18,668
Convertible preferred stock warrant liability	12
Total liabilities	41,804
Commitments and contingencies (Note 7)	
Convertible preferred stock, \$0.001 par value, 130,909,906 shares authorized as of December 31, 2018; 126,490,496 shares issued and outstanding as of December 31, 2018; liquidation value of \$145,478 as of December 31, 2018 (Note 10)	140,535
Stockholders' deficit	
Common stock, \$0.001 par value, 180,000,000 shares authorized as of December 31, 2018; 17,195,258 shares issued and outstanding as of December 31, 2018	17
Additional paid-in capital	21,124
Accumulated other comprehensive income	1,333
Accumulated deficit	(189,800)
Total stockholders' deficit	(167,326)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 15,013

Pulmonx Corporation

Consolidated Statement of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Year Ended December 31, 2018
Revenue	\$ 20,004
Cost of goods sold	7,718
Gross profit	12,286
Operating expenses	
Research and development	6,991
Selling, general and administrative	20,347
Total operating expenses	27,338
Loss from operations	(15,052)
Interest income	21
Interest expense	(2,520)
Other income (expense), net	(916)
Net loss before tax	(18,467)
Income tax expense	12
Net loss	(18,479)
Other comprehensive income (loss)	
Currency translation adjustment	126
Total other comprehensive income (loss)	126
Comprehensive loss	\$ (18,353)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.10)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	16,748,545

Pulmonx Corporation

Consolidated Statement of Convertible Preferred Stock and Stockholders' Deficit

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
<b>Balances at January 1, 2018</b>	126,411,651	\$ 140,452	17,013,718	\$ 16	\$ 20,704	\$ 1,207	\$ (171,321)	\$ (149,394)
Issuance of Series C-1 convertible preferred stock upon exercise of warrants	78,845	83	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	181,540	1	30	—	—	31
Change in shares subject to repurchase	—	—	—	—	24	—	—	24
Stock-based compensation expense	—	—	—	—	366	—	—	366
Currency translation adjustment	—	—	—	—	—	126	—	126
Net loss	—	—	—	—	—	—	(18,479)	(18,479)
<b>Balances at December 31, 2018</b>	<u>126,490,496</u>	<u>\$ 140,535</u>	<u>17,195,258</u>	<u>\$ 17</u>	<u>\$ 21,124</u>	<u>\$ 1,333</u>	<u>\$ (189,800)</u>	<u>\$ (167,326)</u>

**Pulmonx Corporation**  
**Consolidated Statement of Cash Flows**  
(in thousands)

	Year Ended December 31, 2018
<b>Cash flows from operating activities</b>	
Net loss	\$ (18,479)
Adjustments to reconcile net loss to net cash used in operating activities	
Stock-based compensation expense	366
Change in fair value of convertible preferred stock warrant liability	12
Change in fair value of derivative liability	642
Allowance for doubtful accounts	(15)
Inventory write-downs	297
Depreciation and amortization expense	270
Amortization of debt discount and debt issuance costs	36
<b>Net changes in operating assets and liabilities:</b>	
Accounts receivable	(262)
Inventory	(1,245)
Prepaid expenses and other current assets	21
Other assets	18
Accounts payable	(648)
Accrued liabilities	928
Income taxes payable	(34)
Deferred rent	(62)
Deferred tax liability	(200)
Deferred revenue	(39)
Net cash used in operating activities	(18,394)
<b>Cash flows from investing activities</b>	
Maturities of investments	500
Purchases of property and equipment	(316)
Proceeds from sale of property and equipment	16
Net cash provided by investing activities	200
<b>Cash flows from financing activities</b>	
Proceeds from the issuance of convertible note, related party	12,000
Proceeds from exercise of warrants for Series C-1 convertible preferred stock	83
Proceeds from exercise of common stock options	31
Net cash provided by financing activities	12,114
Effect of exchange rate changes on cash and cash equivalents	154
Net decrease in cash and cash equivalents	(5,926)
Cash and cash equivalents at beginning of year	10,050
Cash and cash equivalents at end of year	\$ 4,124
<b>Supplemental non-cash items:</b>	
Increase (lapse) in repurchase rights of common stock	\$ 24
Accrued interest for convertible note	\$ 738
<b>Supplemental disclosure of cash flow information:</b>	
Cash paid for income taxes	\$ 226
Cash paid for interest	\$ 1,361



## **1. Formation and Business of the Company**

### ***The Company***

Pulmonx Corporation (the “Company”) was incorporated in the state of California in December 1995 as Pulmonx and reincorporated in the state of Delaware in December 2013. The Company is a commercial-stage medical technology company that provides a minimally invasive treatment for patients with severe emphysema, a form of chronic obstructive pulmonary disease (COPD). The Company’s solution, which is comprised of the Zephyr Endobronchial Valve (Zephyr Valve), the Chartis Pulmonary Assessment System (Chartis System) and the StratX Lung Analysis Platform (StratX Platform), is designed to treat a broad pool of patients for whom medical management has reached its limits and either do not want or are ineligible for surgical approaches. The Company has subsidiaries in the Cayman Islands, Germany, Switzerland, Australia, the United Kingdom, the Netherlands, Italy and Hong Kong.

### ***Liquidity and Going Concern***

The Company has incurred operating losses to date and has an accumulated deficit of \$189.8 million as of December 31, 2018. During the year ended December 31, 2018, the Company used \$18.4 million of cash in its operating activities and, as of December 31, 2018, had cash and cash equivalents of \$4.1 million. Historically, the Company’s activities have been financed through private placements of equity securities and debt. The Company has continued to generate operating losses through December 31, 2018. Subsequent to the balance sheet date, the Company has raised \$40.0 million in equity financing (Note 16). The Company’s history of recurring losses, negative cash flows since inception and the need to raise additional funding to finance its operations raise substantial doubt about Company’s ability to continue as a going concern. The Company’s ability to continue as a going concern requires that the Company obtains sufficient funding to finance its operations. In the event the Company does not complete an IPO, the Company plans to continue to fund its operations and capital funding needs through a combination of private equity offerings, debt financings and other sources, including potential collaborations, licenses and other similar arrangements. If the Company is not able to secure adequate additional funding when needed, the Company will need to reevaluate its operating plan and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs or cease operations entirely. These actions could materially impact the Company’s business, results of operations and future prospects. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future. Having insufficient funds may also require the Company to delay, scale back or eliminate some or all of its development programs or relinquish rights to its technology on less favorable terms than it would otherwise choose. The foregoing actions and circumstances could materially impact the Company’s business, results of operations and future prospects.

Therefore, there is substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. They do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America (“GAAP”).

***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Significant estimates and assumptions include reserves and write-downs related to accounts receivable, inventories, the recoverability of long term assets, valuation of equity instruments and equity-linked instruments, valuation of common stock, stock-based compensation, valuation of the convertible preferred stock warrant liability and derivative liability, intangible assets, goodwill, debt and related features, deferred tax assets and related valuation allowances and impact of contingencies.

***Fair Value of Financial Instruments***

The carrying amounts of the Company's financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. The convertible preferred stock warrant liability and derivative liability are carried at fair value based on unobservable market inputs. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the term loan and convertible note payable to related party approximates their fair value (Note 4).

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents, which include money market funds.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents balances with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation ("FDIC") insured limits.

The Company earns revenue from the sale of its products to distributors and other customers such as hospitals. The Company's accounts receivable are derived from revenue earned from distributors and customers. The Company performs ongoing credit evaluations of its customers' and distributors' financial condition and generally requires no collateral from its customers and distributors. At December 31, 2018, no customer or distributor accounted for more than 10% of accounts receivable or revenue.

The Company relies on single source suppliers for the components, sub-assemblies and materials for its products. These components, sub-assemblies and materials are critical and there are no or relatively few alternative sources of supply. The Company's suppliers have generally met the Company's demand for their products and services on a timely basis in the past.

### ***Accounts Receivable and Allowances***

Accounts receivable are recorded at the amounts billed less estimated allowances for doubtful accounts. The Company continually monitors customer payments and maintains an allowance for estimated losses resulting from a customer's inability to make required payments. Company considers factors such as historical experience, credit quality, age of the accounts receivable balances, geographic related risks and economic conditions that may affect a customer's ability to pay. As of December 31, 2018, accounts receivable is presented net of an allowance for doubtful accounts of less than \$0.1 million.

### ***Inventories***

Inventories are valued at the lower of cost to purchase or manufacture the inventory or net realizable value. Cost is determined using the first-in, first-out method ("FIFO") for all inventories. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company records write-downs of inventories which are obsolete or in excess of anticipated demand or market value based on consideration of product lifecycle stage, technology trends, product development plans and assumptions about future demand and market conditions. Inventory write-downs reduce the carrying value of inventory to its net realizable value.

### ***Property and Equipment, Net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, generally between three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or useful economic life of the asset. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet, and any resulting gain or loss is reflected in operations in the period realized.

### ***Impairment of Long-lived Assets***

The Company evaluates its long-lived assets for indicators of possible impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value or discounted estimates of future cash flows. The Company has not identified any such impairment losses to date.

### ***Goodwill***

Goodwill represents the excess of the purchase price over the fair value of net tangible and identified intangible assets acquired in a business combination. Goodwill is not amortized but is evaluated at least annually for impairment or when a change in facts and circumstances indicate that the fair value of the goodwill may be below its carrying value.

The Company tests goodwill for impairment at the reporting unit level ("Reporting Unit"). The Company has determined that it has only one operating segment and one Reporting Unit. The operating results are reviewed only on a consolidated basis to make decisions about resources to be allocated and assess performance. Accordingly, goodwill is tested for impairment in a two-step process. First, the Company determines if the carrying amount of the Reporting Unit exceeds the fair value of the Reporting Unit, which may initially indicate that goodwill could be impaired. If the Company determines that such impairment could have occurred, the Company performs step two and compares the implied fair value of the goodwill to its carrying amount to determine the impairment loss, if any. Estimations and assumptions regarding the future performance and results of the Company's operations, including estimates related to future sales growth, gross margin and operating expenses, and the fair value of the Company's common stock are used in the impairment assessment. Circumstances that could reasonably be expected to negatively affect the key assumptions related to the impairment assessment include but are not limited to, (1) a

significant adverse change in legal factors affecting our existing and future products or in business climate, (2) unanticipated competition, (3) an adverse action or assessment by a regulator, or (4) an adverse change in market conditions that are indicative of a decline in the fair value of the goodwill balance.

#### ***Intangible Assets***

Intangible assets consist of developed technology and trademarks. Intangible assets were recorded at their fair values at the date of acquisition and are amortized using the straight-line method over a 15-year useful life (Note 5).

#### ***Leases***

The Company leases its facilities and meets the requirements to account for these leases as operating leases. For facility leases that contain rent escalations or rent concession provisions, the Company records its rent expense during the lease term on a straight-line basis over the term of the lease. The Company records the difference between the rent paid and the straight-line rent as a deferred rent liability. Leasehold improvements funded by landlord incentives or allowances are recorded as leasehold improvement assets and a corresponding deferred rent liability. The leasehold improvement asset is amortized over the lesser of the term of the lease or life of the asset. The deferred rent liability is amortized on a straight-line basis as a reduction to rent expense over the term of the lease agreement.

#### ***Convertible Preferred Stock***

The Company records all shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, in certain events considered not solely within the Company's control, such as a merger, acquisition or sale of all or substantially all of the Company's assets (each, a "deemed liquidation event"), the convertible preferred stock will become redeemable at the option of the holders of at least a majority of the then outstanding such shares. The Company has not adjusted the carrying values of the convertible preferred stock to its liquidation preference because a deemed liquidation event obligating the Company to pay the liquidation preferences to holders of shares of convertible preferred stock is not probable. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a deemed liquidation event will occur.

#### ***Convertible Preferred Stock Warrants***

The Company's convertible preferred stock warrants require liability classification and accounting as the underlying convertible preferred stock is considered contingently redeemable and may obligate the Company to transfer assets to the holders at a future date upon occurrence of a deemed liquidation event. The convertible preferred stock warrants are recorded at fair value upon issuance and are subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in the consolidated statement of operations and comprehensive loss. The Company will continue to adjust the convertible preferred stock warrant liability for changes in fair value until the earlier of the exercise or expiration of the convertible preferred stock warrants, occurrence of a deemed liquidation event or conversion of convertible preferred stock into common stock.

If all outstanding shares of the series of convertible preferred stock for which the convertible preferred stock warrants are exercisable for are converted to shares of common stock or any other security, then thereafter (a) the convertible preferred stock warrants shall become exercisable for such number of shares of common stock or such other security as is equal to the number of shares of common stock or such other security that each share of convertible preferred stock was converted into, multiplied by the number of shares subject to the convertible preferred stock warrants immediately prior to such conversion, and (b) the exercise price of the convertible preferred stock warrants shall automatically be adjusted to equal the number obtained by dividing (1) the aggregate exercise price for which the convertible preferred stock warrants were exercisable immediately prior to such conversion by (2) the number of shares of common stock or such other security for which the convertible preferred stock warrants are exercisable immediately after such conversion.

### **Revenue Recognition**

The Company's revenue is generated from the sale of its products to distributors and hospitals in the United States and international markets.

On January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, using the full retrospective method. In connection with the adoption of ASC 606, the Company also adopted the related amendments that impact the accounting for the incremental costs of obtaining a contract.

Under ASC 606, revenue is recognized when the customer obtains controls of promised goods or services, in an amount that reflects consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps as prescribed by ASC 606:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the entity satisfies performance obligations.

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer that defines each party's rights regarding the products or services to be transferred and identifies the payment terms related to these products or services, (ii) the contract has commercial substance and, (iii) the Company determines that collection of substantially all consideration for products or services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company identifies performance obligations in contracts with customers, which may include its products and implied promises to provide free products and analysis services for patient scans. The transaction price is determined based on the amount expected to be entitled to in exchange for transferring the promised services or product to the customer. The Company is entitled to the total consideration for the products ordered by customers, net of early pay discounts, volume rebate adjustments and other transaction price adjustments. The Company's payment terms to customers generally range from 30 to 60 days. Payment terms fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Assuming all other revenue recognition criteria are met, revenue is recognized when control of the Company's products transfers to the customer. For sales where the Company's sales representative hand delivers product directly to the hospital or medical center control transfers to the customer upon this delivery. For sales where products are shipped, control is transferred either upon shipment or delivery of the products to the customer, depending on the shipping terms and conditions. For consignment sales, control is transferred when the products are used by the customer in procedures. The Company defers revenue relating to any remaining performance obligations by the Company to the customer after delivery, such as free products and free analysis services of patient scans to determine suitability of the patients for the treatment using the Company's Zephyr Valves. As permitted under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less.

The Company accepts product returns at its discretion or if the product is defective as manufactured. Historically, the actual product returns have been immaterial to the Company's financial statements. The Company elected to treat shipping and handling costs as a fulfillment cost and include them in the cost of goods sold as incurred. In

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those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed within revenue.

The Company disaggregates its revenue by major geographic region, which has been disclosed in Note 13, "Segment Information".

The Company's contract liabilities consists of deferred revenue for remaining performance obligations by the Company to the customer after delivery, which was \$0.1 million as of December 31, 2018. The deferred revenue as of December 31, 2017 was \$0.2 million, which was recognized during the year-ended December 31, 2018.

The Company elected the following practical expedients allowed upon adoption of ASC 606:

- (i) The Company did not restate contracts that began and were completed within the same annual reporting period;
- (ii) For completed contracts that have variable consideration, the Company used the transaction price at the date the contract was completed rather than estimating variable consideration amounts in the comparative reporting periods;
- (iii) For all reporting periods presented before the date of initial application, the Company did not disclose the amount of the transaction price allocated to the remaining performance obligations and when the Company expects to recognize that amount as revenue; and
- (iv) For contracts that were modified before the beginning of the earliest reporting period presented in accordance with ASC 606, the Company did not retrospectively restate the contract for those contract modifications. Instead, the Company reflected the aggregate effect of all modifications that occurred before the beginning of the earliest period presented in accordance with ASC 606 when:
  - i. Identifying satisfied and unsatisfied performance obligations;
  - ii. Determining the transaction price; and
  - iii. Allocating the transaction price to the satisfied and unsatisfied performance obligations.

The Company recognized the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of accumulated deficit. The cumulative effect of the changes made to the consolidated balance sheet and consolidated statement of convertible preferred stock and stockholders' deficit as of January 1, 2018 for the adoption of ASC 606 were as follows (in thousands):

	Balances Before Adoption of ASC 606	Adjustments due to ASC 606	Balances as Reported Under ASC 606
Inventories	\$ 2,166	\$ 233	\$ 2,399
Deferred costs	558	(558)	—
Deferred revenue	(753)	576	(177)
Accumulated deficit	\$ (171,572)	\$ 251	\$ (171,321)

Costs associated with product sales include commissions. The Company applies the practical expedient and recognizes commissions as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense.

### ***Cost of Goods Sold***

The Company manufactures certain products at its facility and purchases other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and subassemblies, third-party costs, manufacturing overhead costs, direct labor, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. A significant portion of the Company's cost of goods sold currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, 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 of compensation costs, stock-based compensation, engineering and research expenses, clinical trials and related expenses, regulatory expenses, manufacturing expenses incurred to build products for testing, allocated facilities costs, consulting fees and other expenses incurred to sustain the Company's overall research and development programs. All research and development costs are expensed as incurred.

Clinical trial costs are a significant component of the Company's research and development expenses. The Company has a history of contracting with third parties that perform various clinical trial activities on the Company's behalf in the ongoing development of its product candidates. The financial terms of these contracts are subject to negotiations and may vary from contract to contract and may result in uneven payment flow. The Company accrues and expends costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company determines these estimates through discussion with internal personnel and outside service providers as to progress or stage of completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services.

### ***Advertising Costs***

The Company expenses the costs of advertising as incurred. Advertising expenses were \$0.1 million for the year ended December 31, 2018.

### ***Foreign Currency Translation and Transaction Gains and Losses***

The functional currencies of the Company's wholly owned subsidiaries in the Cayman Islands and the Netherlands are the U.S. dollar. The functional currencies of the Company's wholly owned subsidiaries in Switzerland, Germany, Australia, the United Kingdom and Hong Kong are the Swiss franc. The functional currency of the Company's subsidiary in Italy is the Euro. Accordingly, asset and liability accounts of Switzerland, Germany, Australia, the United Kingdom, Italy and Hong Kong operations are translated into U.S. dollars using the current exchange rate in effect at the balance sheet date and equity accounts are translated into U.S. dollars using historical rates. The revenues and expenses are translated using the average exchange rates in effect during the period, and gains and losses from foreign currency translation adjustments are included as a component of accumulated other comprehensive income in the consolidated balance sheet. Foreign currency translation adjustments are recorded in other comprehensive income (loss) in the consolidated statement of operations and comprehensive loss and was \$0.1 million during the year ended December 31, 2018.

Foreign currency transaction gains and losses are included in other income (expense), net in the consolidated statement of operations and comprehensive loss and was \$0.3 million during the year ended December 31, 2018.

### ***Stock-Based Compensation***

The Company accounts for stock-based compensation arrangements with employees in accordance with ASC 718, *Compensation—Stock Compensation*, using a fair-value based method. The Company determines the fair value of stock options on the date of grant using the Black-Scholes option pricing model. The Company's determination of the fair value of stock options is impacted by its common stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the expected term that options will remain outstanding, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

The fair value of time-based awards is recognized over the period during which an option holder is required to provide services in exchange for the option award, known as the requisite service period, which is typically the vesting period using the straight-line method. The fair value of performance-based awards is recognized over the requisite service period using the graded vesting method. Upon the adoption of Accounting Standards Update ("ASU") 2016-09 for periods after January 1, 2018, the Company no longer records estimated forfeitures on share-based awards and, instead, have elected to record forfeitures as they occur.

The Company issued stock options in exchange for the receipt of goods or services from nonemployees. Costs for such equity instruments are measured at the fair value of the equity instruments issued on the measurement date. The value of equity instruments issued to nonemployees is determined on the earlier of the date on which there first existed a firm commitment for performance by the provider of goods and services or on the date performance is complete, using the Black-Scholes option pricing model. The Company believes that the fair value of the equity instrument is more reliably measured than the fair value of the services received. The measurement of stock-based compensation issued to nonemployees is subject to periodic adjustment as the underlying equity instruments vest. The fair value of options granted nonemployees is expensed when vested.

### ***Income Taxes***

The Company accounts for income taxes under the liability method, whereby deferred tax assets and liabilities are determined based on the difference between the consolidated financial statements and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets when management estimates, based on available objective evidence, that it is more likely than not that the benefit will not be realized for the deferred tax assets.

The Company also follows the provisions of ASC 740-10, *Accounting for Uncertainty in Income Taxes*. ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded on the consolidated financial statements. It is the Company's policy to include penalties and interest expense related to income taxes as part of the provision for income taxes.

### ***Net Loss per Share Attributable to Common Stockholders***

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible preferred stock, stock options, common stock subject to repurchase related to early exercise of stock options, convertible preferred stock warrants and convertible note are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security because it participates in dividends



with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities, because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of convertible preferred stock and the holders of the shares issued upon early exercise of stock options subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

### ***Comprehensive Loss***

The Company is required to report all components of comprehensive loss, including net loss, in the financial statements in the period in which they are recognized. Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions and other events and circumstances from non-owner sources. The Company's currency translation adjustment is the main component of other comprehensive loss that is excluded from the reported net loss for all periods presented.

## **3. Recent Accounting Pronouncements**

### ***Recently Adopted Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will supersede most current revenue recognition guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. Since May 2014, the FASB has issued several amendments to the standard. This new standard is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The guidance permits the use of either a retrospective or cumulative effect transition method. The Company adopted ASU 2014-09 using the full retrospective method as of January 1, 2018. The additional disclosures required by the new standard have been included in Note 2, "Summary of Significant Accounting Policies."

In March 2016, the FASB issued ASU 2016-09, *Stock Compensation – Improvements to Employee Share-Based Payment Accounting*. The amendments in this ASU are intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax consequences, classification on the consolidated statement of cash flows and treatment of forfeitures. The amendments in this ASU are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company adopted ASU 2016-09 as of January 1, 2018 and the adoption had no material impact on the Company's consolidated financial statements.

### ***Recent Accounting Pronouncements Not Yet Adopted***

In August 2018, FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU amends the disclosure requirement in ASC 820, *Fair Value Measurement*, by adding, changing or removing certain disclosures. This ASU applies to all entities that are required under this guidance to provide disclosure about recurring or nonrecurring fair value measurements. The amendments require new disclosures related to: changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period; range and weighted-average of significant unobservable inputs used to develop Level 3 fair value measurements. In addition, there are certain changes in disclosure requirements in the existing guidance. For all entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In June 2018, FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This ASU aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share based payment to employees. Under this ASU, the measurement of equity-classified nonemployee awards will be fixed at the grant date, which may lower their cost and reduce volatility in the statement of operations and comprehensive loss. The transition method provided by this ASU is on a modified retrospective basis, which recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. This ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but may take place no earlier than a company's adoption date of ASC 606, *Revenue from Contracts with Customers*. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In July 2017, FASB issued ASU 2017-11, *Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This ASU simplifies the accounting for certain financial instruments with down round features, a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. Down round features are common in warrants, preferred shares and convertible debt instruments issued by private companies and early-stage public companies. This ASU requires companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The amendments in Part I of this ASU are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The amendments in Part I should be applied (1) retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the first fiscal year and interim periods; (2) retrospectively to outstanding financial instruments with a down round feature for each prior reporting period presented. The amendments in Part II of this ASU do not require any transition guidance because those amendments do not have an accounting effect. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other: Simplifying the Test for Goodwill Impairment*. The amendments eliminate Step 2 from the goodwill impairment test. The annual, or interim, goodwill impairment test is performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit should be considered when measuring the goodwill impairment loss, if applicable. The amendments also eliminate the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The new standard is effective for fiscal years beginning after December 15, 2021, and interim periods within that fiscal year. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This ASU requires changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. This ASU requires adoption on a retrospective basis. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*. This new guidance will require financial instruments to be measured at amortized cost, and trade accounts receivable to be presented at the

net amount expected to be collected. The new model requires an entity to estimate credit losses based on historical information, current information and reasonable and supportable forecasts, including estimates of prepayments. In November 2019, the FASB issued ASU 2019-10, which delays the adoption dates for ASU 2016-13 for non-public entities. The new standard is effective for fiscal years beginning after December 15, 2022, and interim periods within that fiscal year. Early adoption is permitted. The Company is currently evaluating the impact of the new standard on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842) (“ASC 842”)*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, which provides clarification to ASU 2016-02. In March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. In November 2019, the FASB issued ASU 2019-10, which delays the adoption dates for ASU 2016-02 for non-public entities. These ASUs (collectively the “new leasing standard”) requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASC 842 supersedes the previous leases standard, ASC 840, *Leases*. The new leasing standard is effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years after December 15, 2021. Early adoption is permitted. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows entities to elect an optional transition method where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoption rather than in the earliest period presented. The Company expects to recognize a right-of-use asset and corresponding lease liability for its operating leases upon adoption. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

#### **4. Fair Value Measurements**

Assets and liabilities recorded at fair value in the consolidated financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels which are directly related to the amount of subjectivity associated with the inputs to the valuation of these assets or liabilities are as follows:

Level 1 – unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2 – inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

Level 3 – unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

*Assets and Liabilities Measured and Recorded at Fair Value on a Recurring Basis* – Financial assets and liabilities held by the Company measured at fair value on a recurring basis include money market funds, convertible preferred stock warrant liability and derivative liability.

*Assets and Liabilities Measured and Recorded at Fair Value on a Nonrecurring Basis* – The Company determines the fair value of long-lived assets held and used, such as intangible assets, by reference to independent appraisals, quoted market prices (e.g. an offer to purchase) and other factors. An impairment charge is recorded when the carrying value of the asset exceeds its fair value. As noted above, there have been no impairment charges recorded to

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date. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the term loan and convertible note payable to related party approximates their fair value and is classified as a Level 2 liability.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis as of December 31, 2018, within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The following table summarizes the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 51	\$ —	\$ —	\$ 51
Total financial assets	51	—	—	51
<b>Liabilities:</b>				
Preferred stock warrant liability	—	—	12	12
Derivative liability	—	—	642	642
Total financial liabilities	\$ —	\$ —	\$ 654	\$ 654

The Company values the convertible preferred stock warrant liability (Note 9) using the Black-Scholes Merton option-pricing model. The expected term for these warrants is based on the remaining contractual life of these warrants. The expected volatility assumption was determined by examining the historical volatility for industry peers, as the Company does not have a trading history for its common stock. The risk-free interest rate assumption is based on U.S. Treasury investments whose term is consistent with the expected term of the warrants. The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

The fair value of the Series C-1 convertible preferred stock warrants was determined using the following assumptions:

	December 31, 2018
Risk-free interest rate	2.63%
Remaining contractual life (in years)	1.11
Dividend yield	0%
Volatility	46%

The derivative liability is associated with the Company's Success Fee Agreement with Oxford Finance LLC (Note 6). The Company values this derivative liability based on the Success Fee amount of \$1.9 million and the probability and estimated timing of a liquidity event. As of December 31, 2018, the probability of occurrence of a Liquidity Event was estimated to be up to 40% before the expiration of the agreement. Changes in the estimated probability may result in an increase or decrease in the fair value of the derivative liability.

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The change in fair value of the convertible preferred stock warrant liability and derivative liability is summarized below (in thousands):

	Convertible Preferred Stock Warrant Liability	Derivative Liability
Beginning fair value, January 1, 2018	\$ —	\$ —
Change in fair value	12	642
Ending fair value, December 31, 2018	<u>\$ 12</u>	<u>\$ 642</u>

**5. Balance Sheet Components**

***Cash and Cash Equivalents***

The Company's cash and cash equivalents consist of the following (in thousands):

	December 31, 2018
Cash	\$ 4,073
Cash equivalents:	
Money market funds	51
Total cash and cash equivalents	<u>\$ 4,124</u>

***Inventory***

Inventory consists of the following (in thousands):

	December 31, 2018
Raw materials	\$ 811
Work in process	100
Finished goods	2,409
Total inventory	<u>\$ 3,320</u>

***Prepaid Expenses and Other Current Assets***

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2018
Prepaid expenses	\$ 146
Prepaid insurance	172
VAT receivable	471
Other current assets	125
Total prepaid expenses and other current assets	<u>\$ 914</u>

***Property and Equipment, Net***

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

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	<b>December 31, 2018</b>
Machinery and equipment	\$ 1,068
Computer equipment and software	813
Furniture and fixtures	233
Leasehold improvements	6
<b>Total</b>	<b>2,120</b>
Less: accumulated depreciation	(1,745)
<b>Property and equipment, net</b>	<b>\$ 375</b>

Depreciation expense for the years ended December 31, 2018 was \$0.1 million.

**Goodwill**

Goodwill was \$2.3 million as of December 31, 2018 arising from the Company's acquisition of the assets of Emphasys Medical, Inc, in March 2009. No goodwill impairment losses have been recognized since the acquisition. There were no acquisitions or dispositions of goodwill in 2018. The Company performed an annual test for goodwill impairment in the fourth quarter of the fiscal year ended December 31, 2018 and determined that goodwill was not impaired.

**Intangible Assets**

Intangible assets consist of the following (in thousands):

	<b>December 31, 2018</b>		
	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Value</b>
Developed technology	\$ 1,658	\$ (1,078)	\$ 580
Trademarks	191	(124)	67
<b>Total intangible assets</b>	<b>\$ 1,849</b>	<b>\$ (1,202)</b>	<b>\$ 647</b>

Amortization expense relating to the intangibles totaled \$0.1 million during 2018.

Future amortization expense is as follows (in thousands):

*Year Ending December 31,*

2019	\$ 123
2020	123
2021	123
2022	123
2023	123
Thereafter	32
<b>Total amortization expense</b>	<b>\$ 647</b>

**Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	<b>December 31, 2018</b>
Accrued employee bonuses	\$ 1,771
Accrued vacation	830
Other accrued personnel related expenses	562
Accrued professional fees	338
Accrued interest	1,313
Sales taxes, franchise tax and VAT	682
Other	380
Total accrued liabilities	\$ 5,876

**6. Long Term Debt and Convertible Notes**

**Term Loan**

In August 2014, the Company entered into a Loan and Security Agreement with Oxford Finance LLC for up to \$20.0 million in term loans. In 2014, the Company borrowed \$15.0 million and had the ability to draw an additional \$5.0 million conditioned upon the achievement of a revenue milestone. The period during which the Company could draw an additional \$5.0 million ended on November 30, 2015 without the Company borrowing the additional \$5.0 million. The term loan bore interest at 8.96% and had a five-year term. The first 36 months were interest only payments followed by 24 months of equal payments of principal and interest. A final payment of 8.50% of the term loan amount is due at maturity and is being accreted using the effective interest rate method. The term loan is collateralized by assets, including cash and cash equivalents, accounts receivable and property and equipment.

In May 2017, the Company entered into a First Amendment to Loan and Security Agreement that extended the interest only period through June 2018 and included an additional fee of \$0.1 million due upon maturity. The amendment was accounted for as a debt modification and no gain or loss is recognized in the Company's financial statements.

In May 2018, the Company entered into Second and Third Amendments to Loan and Security Agreement that extended the interest only period through May 2019 and the maturity date to July 1, 2020. The amendment was accounted for as a debt modification and no gain or loss is recognized in the Company's financial statements. The Company has the option to further extend the interest only period through March 2020 and the maturity date to May 1, 2021, provided that no event of default has occurred. The loan bears interest at an annual rate equal to the greater of (i) 8.71% and (ii) the sum of (a) the greater of the one month U.S. LIBOR rate on the last business day of the month that immediately precedes the month in which the interest will accrued and 1.85% plus (b) 6.86%. The incremental amendment fee, due at maturity, is \$0.4 million and will be increased to \$0.8 million if the Company extends the interest only period through March 2020. As of December 31, 2018, the term loan had an annual effective interest rate of 11.17% per year.

In connection with the original agreement in August 2014, the Company also entered into the Success Fee Agreement. In the event of a sale or other disposition by the Company of all or substantially all of its assets, a merger or consolidation, or an initial public offering (a "Liquidity Event"), before the termination of the agreement on August 28, 2021, the Company is required to pay up to \$2.5 million (the "Success Fee") to Oxford Finance LLC. The Success Fee is equal to 6.25% of the term loan if the Liquidity Event occurs within 18 months of August 28, 2014, 8.75% if the Liquidity Event occurs after 18 months and within 3 years of August 28, 2014, and 12.50% if the Liquidity Event occurs after the third anniversary of August 28, 2014. As of December 31, 2018, the maximum

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amount of Success Fee subject to a potential payout is \$1.9 million. This agreement has been identified as a freestanding derivative under ASC 815, *Derivatives* and is remeasured to its fair value at the end of each reporting period and any change in fair value is recognized as change in other income (expense), net in the statement of operations and comprehensive loss (Note 4). The fair value of the derivative liability as of December 31, 2018 was \$0.6 million.

The term loan consists of the following (in thousands):

	<b>December 31, 2018</b>
Term loan	\$ 15,000
Less: debt issuance costs	(48)
Less: deferred financing costs	(15)
Term loan	\$ 14,937

Future payments under term loan, including interest only payments and the final payment, are as follows (in thousands):

<i>Year Ending December 31,</i>		
2019	\$	8,487
2020		9,722
Total		18,209
Less: unamortized debt discount		(63)
Less: interest		(3,209)
Term loan	\$	14,937

The Company incurred fees and legal expenses of \$0.1 million in connection with the Agreement and Amendments, which are recorded as deferred financing costs and amortized to interest expense. The Company also paid \$0.2 million in fees to the lender which is reflected as a discount on the debt and is being accreted over the life of the term loan. In 2018, the Company recorded interest expense related to deferred financing and debt issuance costs of less than \$0.1 million.

Interest expense on the term loan amounted to \$1.7 million year ended December 31, 2018. The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. As of December 31, 2018, the Company is in compliance with all the covenants contained in the Loan and Security Agreement.

In May 2019, the Company elected to extend the interest only period of the term loan through March 2020 and the maturity date to May 2021.

**Convertible Note**

In May 2017, the Company entered into a Second Lien Loan and Security Agreement with Boston Scientific Corporation, an investor, for up to \$30.0 million in term loans. The loans under this agreement are subordinated to the term loan with Oxford Finance LLC and are also collateralized by assets, including cash and cash equivalents, accounts receivable and property and equipment. Under the Agreement, Boston Scientific Corporation agreed to make one or more term loans to the Company during the period beginning in May 2017 and ending on May 13, 2022, the maturity date (the "Term Loans"). The principal amount outstanding under the Term Loans drawn prior to June 30, 2018 accrue no interest from the date of such Term Loan through and including June 30, 2018. Beginning on July 1, 2018, all Term Loans accrue interest at a fixed rate of 8.96%. Interest accrues until such Term Loan is converted to stock or paid in full. Each Term Loan is evidenced by a separate Secured Convertible Promissory Note



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and is repayable, convertible and exchangeable. As of December 31, 2018, the Term Loans had an annual effective interest rate of 7.47% per year.

If the Company completes any Qualified Equity or Debt Financing or any Change of Control, Liquidation or Prepayment Conversion occurs, outstanding principal and accrued interest on the loans are convertible at Boston Scientific Corporation's option into shares of either (1) the Series F-1 convertible preferred stock or, if the shares of Series F-1 convertible preferred stock are not the most senior series of preferred stock of the Company then issued and outstanding (2) the most senior series of preferred stock of the Company then issued and outstanding ("Conversion Stock"). The Conversion Stock Per Share Price is defined as (A) with respect to a Qualified Equity Financing, the lowest price per share of Conversion Stock paid by any investor in such Qualified Equity Financing, (B) with respect to a Change of Control or Liquidation, the total amount distributed, paid or to be paid to the stockholders of the Company on account of the stock held by them in connection with such Change of Control or Liquidation, divided by the fully-diluted share count of the Company on the Conversion Date or (C) with respect to a Prepayment Conversion, \$230,000,000 divided by the fully-diluted share count of the Company on the Conversion Date.

Subject to Boston Scientific Corporation's conversion rights, the Company has the option to prepay all of the Term Loans, at any time.

In conjunction with the Second Lien Loan and Security Agreement, the Company and Boston Scientific entered into a No Shop Agreement such that from the date of execution of the agreement through the earlier of the Company's submission of the final module of its Premarket Approval application to the FDA and March 31, 2018, the Company would not sign a term sheet or engage in discussions to sell the Company. In addition, Boston Scientific's Right of First Negotiation, originally received as part of the Preferred Series F-1 financing, was amended to shorten the period it has to exercise its Right of First Negotiation from 10 to 5 business days, and to shorten the Exclusive Negotiation Period from 75 to 45 days with respect to the initial notice from the Company that it intends to pursue a change in control or IPO. For subsequent notices from the Company, Boston Scientific has 10 days to exercise its right of first negotiation, and 75 days to enter into definitive agreements for a change in control transaction.

The Company borrowed \$12.0 million in 2018.

The convertible note consists of the following (in thousands):

	<b>December 31, 2018</b>
Convertible note	\$ 18,000
Less: debt issuance costs	(98)
Accrued interest	766
Convertible note payable to related party	\$ 18,668

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Future payments under the convertible note as of December 31, 2018, including accrued interest, are as follows (in thousands):

<i>Fiscal Years Ending December 31,</i>	
2019	\$ —
2020	—
2021	—
2022	24,070
<b>Total</b>	<b>24,070</b>
Add: accrued interest, net of unamortized debt issuance cost	668
Less: interest	(6,070)
Convertible note payable to related party	<u>\$ 18,668</u>

In January 2019, the Company borrowed \$6.0 million pursuant to the Second Lien Loan and Security Agreement with Boston Scientific Corporation and all the Term Loans and accrued interest under the agreement converted into shares of Series G-1 convertible preferred stock.

The Company incurred fees and legal expenses of \$0.1 million in connection with the Agreement, which are reported on the balance sheet as a direct deduction from the face amount of the convertible note. Amortization of the issuance costs are calculated using the effective interest rate method over the term of the note and recorded as a non-cash interest expense. In 2018, the Company accrued interest expense of \$0.8 million, which is included in convertible note payable to related party at December 31, 2018. The Second Lien Loan and Security Agreement contains customary affirmative and negative covenants and events of default. As of December 31, 2018, the Company is in compliance with all the covenants contained in the Second Lien Loan and Security Agreement.

Subsequent to year end, all Secured Convertible Promissory Notes converted into shares of Series G-1 convertible preferred stock (Note 16).

## 7. Commitments and Contingencies

The Company has a lease for its U.S. office facilities through July 2020. The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term and records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Where leases contain escalation clauses, rent abatements or concessions, such as rent holidays and landlord or tenant incentives or allowances, the Company applies them in the determination of straight-line rent expense over the lease term. During 2013, the Company entered into a five-year lease for office facilities in Switzerland which expired in January 2018. In 2017, the Company amended the lease and extended the term through January 2020. Rent expense for the year ended December 31, 2018 was \$1.0 million.

Future minimum lease payments under the non-cancelable operating leases as of December 31, 2018 are as follows (in thousands):

<i>Year Ending December 31,</i>	
2019	\$ 870
2020	489
<b>Total minimum lease payments</b>	<u>\$ 1,359</u>

### **Contingencies**

From time to time, the Company may be a party to various litigation claims in the normal course of business. Legal fees and other costs associated with such actions are expensed as incurred. The Company assesses, in conjunction

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with legal counsel, the need to record a liability for litigation and contingencies. Accrual estimates are recorded when and if it is determinable that such a liability for litigation and contingencies are both probable and reasonably estimable.

In December 2018, a former distributor outside the United States filed suit alleging the Company's subsidiary, PulmonX International Sàrl, conducted unfair competitive practices and violated the exclusive distribution rights as a result of the subsidiary's termination of its distribution agreement. The complaint seeks pecuniary and non-pecuniary damages. The Company is in the initial stages of evaluating this matter and does not believe the impact of any such matter will be material to the Company's results of operation or financial position.

**8. Income Taxes**

Income before the provision for income taxes consists of the following (in thousands):

	<b>Year Ended December 31, 2018</b>
Domestic	\$ (12,527)
Foreign	(5,940)
<b>Total income before provision for taxes</b>	<b>\$ (18,467)</b>

The components of income tax expense are as follows (in thousands):

	<b>Year Ended December 31, 2018</b>
<b>Current:</b>	
Federal	\$ —
State	2
Foreign	207
<b>Total current expense</b>	<b>209</b>
<b>Deferred:</b>	
Federal	(222)
State	4
Foreign	21
<b>Total deferred expense</b>	<b>(197)</b>
<b>Total income tax expense</b>	<b>\$ 12</b>

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The reconciliation between the federal statutory rate and the Company's effective tax rate is summarized below:

	<b>Year Ended December 31, 2018</b>
Federal statutory rate	21.0 %
State taxes, net of federal benefit	1.0 %
Foreign earnings at different rates	(8.0)%
Tax credits	0.9 %
Permanent differences	(0.3)%
Prior year true-up	(2.9)%
Change in valuation allowance	10.7 %
Expiration of net operating loss carryforwards and credits	(22.5)%
Effective tax rate	<u>(0.1)%</u>

Deferred income taxes arise from temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax reporting purposes, as well as operating losses and tax credit carryforwards. Significant components of the Company's deferred tax assets and liabilities for federal and state income taxes are as follows (in thousands):

	<b>December 31, 2018</b>
Deferred tax assets:	
Net operating loss carryforwards	\$ 19,519
Tax credit carryforwards	4,659
Other	850
Gross deferred tax assets	<u>25,028</u>
Less: valuation allowance	(24,736)
Deferred tax assets	<u>292</u>
Deferred tax liabilities:	
Depreciation	(17)
Goodwill	(323)
Net deferred tax liabilities	<u>\$ (48)</u>

The Company has established a full valuation allowance against its U.S. net deferred tax assets due to the uncertainty surrounding the realization of such assets. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the U.S. net deferred tax assets have been fully offset by a valuation allowance of \$24.7 million. The valuation allowance decreased by \$2.0 million for the year ended December 31, 2018.

As of December 31, 2018, the Company had total net operating loss carryforwards for federal income tax purposes of approximately \$83.3 million. If not utilized, these net federal operating loss carryforwards will expire beginning in 2018. The Company also had a state net operating loss carryforward of approximately \$29.4 million which will expire beginning in 2028. The Company also had federal and state research and development ("R&D") tax credit carryforwards of approximately \$2.5 million and \$3.8 million, respectively. The federal tax R&D credit carryforwards will expire beginning in 2030 while the state tax R&D credit carryforwards have no expiration date.

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Utilization of the net operating loss carryforwards and R&D tax credit carryforwards may be subject to annual limitations due to the ownership change limitations provided by the Internal Revenue Code, as defined in Section 382, and other similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. During the year ended December 31, 2018, the Company completed a formal 382 study for which the Company wrote off deferred tax assets for NOLs and credits of \$3.1 million and \$1.2 million, respectively. Since the Company had a full valuation allowance on these assets, there was no material impact to the tax provision.

Undistributed earnings of the Company's foreign subsidiaries amounted to a deficit balance at December 31, 2018. Foreign earnings, if any, are considered to be permanently reinvested and accordingly, no deferred U.S. income taxes have been provided thereon.

Annually, the Company determines whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities in considering whether any tax benefit can be recorded in the consolidated financial statements. As of December 31, 2018, the Company had unrecognized tax benefits of approximately \$0.9 million, none of which will affect the tax rate if recognized. It is unlikely that the amount of liability for unrecognized tax benefits will significantly change over the next 12 months.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits (in thousands):

Balance at December 31, 2017	\$	1,070
Additions for tax positions related to current year		57
Additions for tax positions related to prior year		(185)
Balance at December 31, 2018	\$	<u>942</u>

It is the Company's policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary.

The Company's major tax jurisdictions are the United States and California, Switzerland and Neuchâtel, and Grand Cayman. All of the Company's tax years will remain open for examination by the federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or R&D Credits. The Company does not have any tax audits or other issues pending.

For the year ended December 31, 2018, the Company adopted a change in accounting policy in accordance with ASU 2016-09 to account for excess tax benefits and tax deficiencies as income tax expense or benefit, treated as discrete items in the reporting period in which they occur, and to recognize previously unrecognized deferred tax assets that arose directly from (or the use of which was postponed by) tax deductions related to equity compensation in excess of compensation recognized for financial reporting. The change was applied on a modified retrospective basis; no prior periods were restated as a result of this change in accounting policy.

In December 2017, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provided a measurement period of up to one year from enactment date of the 2017 Tax Act for the Company to complete the accounting for the 2017 Tax Act and its related impacts. The income tax effects of the 2017 Tax Act for which the accounting was incomplete may include: the impact of the transition tax, the revaluation of deferred tax assets and liabilities to reflect the 21% corporate tax rate and the impact to the aforementioned items on state income taxes. During the year ended December 31, 2018, the Company completed its accounting for the 2017 Tax Act and did not recognize any material adjustments to the provisional amounts.

The 2017 Tax Act included the implementation of a modified territorial tax system, which has the effect of subjecting earnings of our foreign subsidiaries to U.S. taxation on Global Intangible Low-Taxed Income ("GILTI"). The FASB allows companies to adopt a policy election to account for the tax on GILTI under one of two methods:

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(i) account for the tax on GILTI as a component of tax expense in the period in which the tax is incurred (the period cost method), or (ii) account for the tax on GILTI in a company's measurement of deferred taxes (the deferred method). The Company has elected to account for the tax on GILTI under the period cost method.

**9. Warrants for Convertible Preferred Stock**

A summary of the outstanding convertible preferred stock warrants as of December 31, 2018 is as follows (in thousands, except per share and share amounts):

Securities into Which Warrants are Exercisable	Exercise Price Per share	Shares	Fair Value of Liability	Expiration Date
Series C-1 convertible preferred stock	\$ 1.057	2,152,939	\$ 12	February 9, 2020

***Series B-1 Convertible Preferred Stock Warrants***

The Series B-1 convertible preferred stock warrants were issued in conjunction with a bank financing in 2008. The Series B-1 convertible preferred stock warrants expired August 24, 2018.

***Series C-1 Convertible Preferred Stock Warrants***

During February through October 2010, the Company issued an aggregate of 31,775,668 shares of Series C-1 convertible preferred stock in exchange for cash of \$21.5 million and the conversion of outstanding convertible promissory notes and accrued interest on notes being converted. Additionally, 2,012,266 shares were issued in conjunction with the terms of a 2009 acquisition. In connection with the issuance of Series C-1 convertible preferred stock, the Company issued warrants to purchase 7,328,294 shares of Series C-1 convertible preferred stock at an exercise price of \$1.057 per share. The Company recorded the fair value of the warrants of \$1.9 million as convertible preferred stock warrant liability. The Company recorded a charge to interest and other expense of \$0.2 million associated with the beneficial conversion feature.

During 2013, warrants to purchase 2,851,563 shares of Series C-1 convertible preferred stock were exercised at an exercise price of \$1.057 per share, yielding \$3.0 million. The Company revalued the warrants immediately prior to exercise and recorded income of \$0.2 million in change in fair value of convertible preferred stock warrant liability in the consolidated statement of operations and comprehensive loss.

During 2015, warrants to purchase 92,005 shares of Series C-1 convertible preferred stock were exercised at an exercise price of \$1.057 per share, yielding \$0.1 million. The Company revalued the warrants immediately prior to exercise and recorded income of less than \$0.1 million in change in fair value of convertible preferred stock warrant liability in the consolidated statement of operations and comprehensive loss.

In June 2015, the Board approved the extension of the maturity date from June 2015 to February 2017 for 323,465 warrants for Series C-1 convertible preferred stock.

In February 2017, the Board approved the extension of the maturity date from February 2017 to February 2018 for 4,384,726 warrants for Series C-1 convertible stock.

In February 2018, the Board amended the warrants to extend the expiration date to February 2020, provided that the share amount exercisable under the warrants decreases by 50% if exercised after February 8, 2018. As the warrants are measured at fair value, the impact of the amendment on the fair value of the warrants was recorded in the statement of operations and comprehensive loss.

In February 2018, warrants to purchase 78,845 shares of Series C-1 convertible preferred stock were exercised at an exercise price of \$1.057 per share, yielding \$0.1 million. Pursuant to the February 2018 warrant amendment, shares issuable upon exercise of the warrants decreased from 4,305,881 to 2,152,939.

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The Company revalued the remaining warrants at December 31, 2018 and the Company recorded expense of less than \$0.1 million in change in other income (expense), net in the consolidated statement of operations and comprehensive loss.

**10. Convertible Preferred Stock**

Under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue up to 130,909,906 shares of convertible preferred stock .

As of December 31, 2018, convertible preferred stock consists of the following (in thousands, except per share and share amounts):

Series	Number of Shares Authorized	Number of Shares Issued and Outstanding	Carrying Value <sup>(1)</sup>	Liquidation Preference per Share	Liquidation Value
Series A-1	8,486,224	8,486,224	\$ 8,135	\$ 0.959	\$ 8,138
Series B-1	24,338,205	24,224,676	23,130	1.057	25,605
Series C-1	41,575,922	37,270,041	37,306	1.057	39,395
Series D-1	9,400,000	9,400,000	10,268	1.100	10,340
Series E-1	9,230,768	9,230,768	11,896	1.300	12,000
Series F-1	37,878,787	37,878,787	49,800	1.320	50,000
<b>Total</b>	<b>130,909,906</b>	<b>126,490,496</b>	<b>\$ 140,535</b>		<b>\$ 145,478</b>

(1) Carrying values above are net of issuance costs

**Dividends**

The holders of Series A-1, Series B-1, Series C-1, Series D-1, Series E-1 and Series F-1 convertible preferred stock are entitled to receive dividends, out of any assets legally available, prior and in preference to any declaration or payment of any dividend on the common stock of the Company, at a rate of \$0.07672, \$0.08456, \$0.08456, \$0.08800, \$0.10400 and \$0.1056 respectively, per share per year (as adjusted for stock splits, stock dividends, reclassifications and similar events) payable quarterly when, and as declared by the Board of Directors and are not cumulative. After payment of such dividends, any additional dividends shall be distributed the holders of Series A-1, Series B-1, Series C-1, Series D-1, Series E-1 and Series F-1 convertible preferred stock and common stock on a pro rata basis. No dividends have been declared to date.

**Liquidation**

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series F-1 convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of the assets of the Corporation or any such consideration to the holders of Series A-1, Series B-1, Series C-1, Series D-1 and Series E-1 convertible preferred stock or the holders of common stock, an amount equal to \$1.32 per share (as adjusted for stock splits, stock dividends, reclassification and similar events) plus any declared but unpaid dividends. If upon the occurrence of such event, the assets and funds available are insufficient to permit the payment to the Series F-1 convertible preferred stockholders of the full preferential amounts, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of Series F-1 convertible preferred stock in proportion to the preferential amount each such holder is otherwise entitled to receive. After the payment in full of the Series F-1 liquidation preference, the holders of the Series E-1 convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of the assets of the Corporation or any such consideration to the holders of Series A-1, Series B-1, Series C-1, and Series D-1 convertible preferred stock or the holders of common stock, an amount equal to \$1.30 per share (as adjusted for stock splits, stock dividends, reclassification and similar events) plus any declared but unpaid dividends. If upon the

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occurrence of such event, after payment in full of the Series F-1 liquidation preference, the assets and funds available are insufficient to permit the payment to the Series E-1 convertible preferred stockholders of the full preferential amounts, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of Series E-1 convertible preferred stock in proportion to the preferential amount each such holder is otherwise entitled to receive. After the payment in full of the Series F-1 liquidation preference and the Series E-1 liquidation preference, the holders of Series A-1, Series B-1, Series C-1 and Series D-1 convertible preferred stock are entitled to receive, prior and in preference to any distribution of the assets of the Corporation or any such consideration to the holders of common stock, an amount equal to \$0.959, \$1.057, \$1.057 and \$1.100 per share (as adjusted for stock splits, stock dividends, reclassification and similar events) plus any declared but unpaid dividends. If upon the occurrence of such liquidation, the assets and funds of the Company legally available for distribution are insufficient to permit payment to such holders, then the entire remaining assets and funds shall be distributed ratably among such holders in proportion to the preferential amounts each such holder is otherwise entitled to receive.

In the event of a Liquidation Transaction involving one or more third parties other than the purchaser of Series F-1 convertible preferred stock and after the payment in full of the liquidation preference required to be paid, the holders of the Series F-1 convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company or any such consideration to the holders of common stock an amount equal to the Additional Preference (as defined below) for each share of Series F-1 preferred stock then held by them. Upon the closing of a Liquidation Transaction, if the amounts earned or payable to the stockholders of the Corporation on or before the one (1) year anniversary of the closing of such Liquidation Transaction is (i) equal to or greater than \$250.0 million but less than \$300.0 million, the Additional Preference is equal to \$0.33 per share (as adjusted for stock splits, stock dividends, reclassifications and the like) for each share of Series F-1 convertible preferred stock then held by them, (ii) equal to or greater than \$300.0 million but less than \$350.0 million, the Additional Preference is equal to \$0.50 per share (as adjusted for stock splits, stock dividends, reclassifications and the like) for each share of Series F-1 preferred stock then held by them, and (iii) equal to or greater than \$350.0 million, the Additional Preference is equal to \$0.66 per share (as adjusted for stock splits, stock dividends, reclassifications and the like) for each share of Series F-1 convertible preferred stock then held by them.

After liquidation preferences to the convertible preferred stockholders have been paid, and after the Additional Preference has been paid, if any, the remaining assets of the Company shall be distributed to the holders of common stock, Series A-1, Series B-1, Series C-1, Series D-1, Series E-1 and Series F-1 convertible preferred stock as if the convertible preferred shares were converted into common stock at then-applicable conversion price until the Series A-1, Series B-1, Series C-1, Series D-1, Series E-1 and Series F-1 convertible preferred stock have received an aggregate amount (including the initial preference amount) equal to \$2.877, \$3.171, \$3.171, \$3.300, \$3.900 and \$3.960 per share (as adjusted for stock splits, stock dividends, reclassifications and similar events) plus any declared and unpaid dividends. The holders of common stock are entitled to receive ratably on a per-share basis all remaining assets.

A liquidation, dissolution or winding up of the Company shall be deemed to be occasioned by, or include, (A) the sale, lease, license on an exclusive basis, conveyance or disposition (whether by merger or otherwise) by the Company of all or substantially all of the assets of the Company, or the sale or disposition of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, or (B) the merger of the Company with or into any other corporation, limited liability company or other entity (other than a wholly-owned subsidiary of the Company); provided that none of the following shall be considered a Liquidation Transaction: (i) a merger effected exclusively for the purpose of changing the domicile of the Company, (ii) an equity financing effected for bona fide capital raising purposes in which the Company is the surviving entity or (iii) any transaction in which the stockholders of the Company immediately prior to the transaction own greater than 50% of the voting power of the Company or such other surviving or resulting entity (or if the Company or such other surviving or resulting entity is a wholly-owned subsidiary immediately following such acquisition, its parent).



### ***Voting***

The holders of convertible preferred stock shall have the same voting rights as the holders of common stock. The holders of common stock and the convertible preferred stock shall vote together as a single class on all matters. Each holder of common stock shall be entitled to one vote for each share of common stock held, and each holder of convertible preferred stock shall be entitled to the number of votes equal to the number of shares of common stock into which such shares of convertible preferred stock could be converted.

As of December 31, 2018, the Board of Directors was comprised of eight members. For so long as there are outstanding at least 500,000 shares of Series A-1 convertible preferred stock (as adjusted for stock splits, reclassifications or similar events), the holders of Series A-1 convertible preferred stock, voting as a separate class, shall be entitled to elect one member of the Company's Board of Directors. For so long as there are outstanding at least 500,000 shares of Series B-1 convertible preferred stock (as adjusted for stock splits, reclassifications or similar events), the holders of Series B-1 convertible preferred stock, voting as a separate class, shall also be entitled to elect two members of the Company's Board of Directors. For so long as there are outstanding at least 500,000 shares of Series C-1 convertible preferred stock (as adjusted for stock splits, reclassifications or other similar transactions), the holders of Series C-1 convertible preferred stock, voting as a separate class, shall be entitled to elect two members of the Company's Board of Directors. The holders of common stock and convertible preferred stock, voting together as a single class on an as-if-converted basis, shall be entitled to elect all remaining members of the Board of Directors.

### ***Conversion***

Each share of convertible preferred stock shall be convertible, at the option of the holder at any time after the date of issuance into the number of fully paid and non-assessable shares of common stock as determined by dividing the original issue price per share of each series of convertible preferred stock by the conversion price per share in effect for the shares of each series of convertible preferred stock at the time of conversion. The original conversion price per share of Series A-1, Series B-1, Series C-1, Series D-1, Series E-1 and Series F-1 convertible preferred stock shall be the original issue price, subject to adjustment, as described in the Company's Amended and Restated Certificate of Incorporation.

Each share of convertible preferred stock shall automatically be converted into shares of common stock at the conversion rate at the time in effect for such share immediately upon the earlier of (i) the Company's sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933 at a price per share of not less than \$5.00 (as adjusted for stock splits, dividends and the like) which results in aggregate cash proceeds to the Company of not less than \$30.0 million (net of underwriting discounts and commissions) or (ii) the date specified by the vote or written consent of the holders of at least a majority of the then outstanding shares of convertible preferred stock, voting together as a single class.

## **11. Stockholders' Deficit**

### ***Common Stock***

The Amended and Restated Certificate of Incorporation authorizes the Company to issue up to 180,000,000 shares of common stock. Common stockholders are entitled to dividends as and when declared by the Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

**Shares Reserved for Future Issuance**

The Company has reserved shares of common stock for future issuances as follows:

	<b>December 31, 2018</b>
Series A-1 convertible preferred stock outstanding	8,486,224
Series B-1 convertible preferred stock outstanding	24,224,676
Series C-1 convertible preferred stock outstanding	37,270,041
Series D-1 convertible preferred stock outstanding	9,400,000
Series E-1 convertible preferred stock outstanding	9,230,768
Series F-1 convertible preferred stock outstanding	37,878,787
Warrants to purchase Series C-1 convertible preferred stock	2,152,939
Convertible note*	—
Common stock options issued and outstanding	26,265,227
Common stock available for future grants	3,826,728

\* The conversion of the convertible notes into common stock is dependent on the outstanding loan balance including accrued interest and the conversion stock per share price at the date of Qualified Equity Financing, Change of Control, Liquidation, or Prepayment Conversion (see Note 6). These factors are not estimable and the number of common stock is not determinable.

**Stock Option Plan**

The Company reserved 45,502,004 shares of its common stock under its 2000 Stock Plan (the “2000 Stock Plan”) and 2010 Stock Plan (the “2010 Stock Plan”). Options granted under the Stock Plans may be either incentive stock options or nonqualified stock options. Incentive stock options (“ISO”) may be granted only to the Company employees (including officers and directors). Nonqualified stock options (“NSO”) may be granted to the Company employees and consultants. As of December 31, 2018, no shares of common stock remain available for issuance to officers, directors, employees and consultants pursuant to the 2000 Stock Plan.

Options to purchase the Company’s common stock may be granted at a price not less than 100% of the fair market value in the case of ISO or NSO, except for an employee or nonemployee with options who owns more than 10% of the voting power of all classes of stock of the Company in which case the exercise price shall be no less than 110% of the fair market value per share on the grant date. Fair market value is determined by the Board of Directors. Options are immediately exercisable and vest as determined by the Board of Directors ranging from immediately upon grant to a rate of 25% per annum over four years from the grant date. Options expire as determined by the Board of Directors but not more than ten years after the date of grant.

Activity under the Company’s stock option plans is set forth below:

	<b>Shares Available for Grant</b>	<b>Outstanding Options</b>	
		<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Balance, January 1, 2018	1,251,912	24,199,788	\$ 0.15
Additional shares reserved	5,021,795	—	—
Options granted	(2,559,000)	2,559,000	0.14
Options exercised	—	(181,540)	0.17
Options canceled <sup>(1)</sup>	112,021	(312,021)	0.16
Balance, December 31, 2018	<u>3,826,728</u>	<u>26,265,227</u>	<u>\$ 0.15</u>

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

(1) Canceled stock options issued under the Company's 2000 Stock Plan were canceled after the 2010 Stock Plan was approved and are not included in the shares available for grant as they were not returned to the stock option pool.

The aggregate intrinsic value of options exercised during the year ended December 31, 2018 was less than \$0.1 million.

The options outstanding, exercisable and vested by exercise price at December 31, 2018 were as follows:

Options Outstanding and Exercisable			Options Exercisable and Vested	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Number Exercisable and Vested	Weighted Average Exercise Price
\$ 0.06	629,000	0.78	629,000	\$ 0.06
\$ 0.13	3,328,694	8.62	1,717,745	\$ 0.13
\$ 0.14	11,442,433	6.69	9,045,764	\$ 0.14
\$ 0.15	8,271,695	7.04	6,408,066	\$ 0.15
\$ 0.20	981,828	2.48	981,828	\$ 0.20
\$ 0.24	414,083	4.67	414,083	\$ 0.24
\$ 0.29	1,197,494	5.67	1,197,494	\$ 0.29
	26,265,227	6.67	20,393,980	

The weighted average exercise price and aggregate intrinsic value of options outstanding and exercisable at December 31, 2018 was \$0.15 per share and \$0.2 million, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money as of December 31, 2018.

	December 31, 2018		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Life (in Years)
Options vested	20,393,980	\$ 0.15	6.22
Options vested and expected to vest	26,265,227	\$ 0.15	6.67

Total intrinsic value of options vested and expected to vest as of December 31, 2018 was \$0.2 million.

**Early Exercise of Stock Options**

Under the terms of the individual option grants, all options are fully exercisable on the grant date, subject to the Company's repurchase right at the original exercise price. Accordingly, options may be exercised prior to vesting. The shares are subject to the Company's lapsing repurchase right upon termination of employment or over the options' vesting period of generally four years at the original purchase price. The proceeds initially are recorded in other liabilities from the early exercise of stock options and are reclassified to additional paid-in capital as the Company's repurchase right lapses. During the year ended December 31, 2018, the Company did not repurchase shares of common stock. As of December 31, 2018, 268,604 shares were subject to repurchase, with an aggregate exercise price of less than \$0.1 million, and were recorded in other current liabilities.

**Stock-Based Compensation for Employees**

During the year ended December 31, 2018, the Company granted stock options to employees to purchase 2,559,000 shares of common stock. The weighted average grant-date fair value of the employee stock options granted during the year ended December 31, 2018 was \$0.14 per share.

The Company uses the Black-Scholes Merton option-pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant is affected by the stock price as well as assumptions regarding a number of complex and subjective variables. These variables include expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rates and expected dividends. The estimated grant date fair values of employee stock options were calculated using the following assumptions:

	<b>Year Ended December 31, 2018</b>
Weighted average expected term (in years)	6.25
Volatility	46%
Risk-free interest rate	2.40%-2.92%
Dividend yield	—

**Expected Term**

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

**Volatility**

The expected stock price volatility assumptions for the Company's stock options for the years ended December 31, 2018 was determined by examining the historical volatilities for industry peers, referred to as "guideline" companies, as the Company did not have any trading history for the Company's common stock. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

**Risk-Free Rate**

The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

**Dividend Yield**

The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

**Fair Value of Common Stock**

The fair value of the Company's common stock is determined by the board of directors with assistance from management and, in part, on input from an independent third-party valuation firm. The board of directors determines the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook.

**Stock-Based Compensation for Non-Employees**

Stock-based compensation expense related to stock options granted to non-employees is recognized on an accelerated basis as the stock options are earned. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The fair value of the stock options granted to non-employees is calculated at each reporting date using the Black-Scholes Merton option-pricing model. During the year ended December 31, 2018, the Company did not grant stock options to non-employees.

Stock-based compensation expense on options granted to non-employees for the years ended December 31, 2018 was less than \$0.1 million.

**Total Stock-Based Compensation**

Stock-based compensation expense is reflected in the statement of operations and comprehensive loss as follows (in thousands):

	<b>Year Ended December 31, 2018</b>
Cost of goods sold	\$ 18
Research and development	62
Selling, general and administrative	286
Total	\$ 366

As of December 31, 2018, there was \$0.4 million of unrecognized compensation costs related to non-vested common stock options, expected to be recognized over a weighted-average period of 1.86 years. The total grant date fair value of shares vested during the year ended December 31, 2018 was \$0.4 million.

**12. Net Loss per Share Attributable to Common Stockholders**

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which excludes shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share amounts):

	<b>Year Ended December 31, 2018</b>
<b>Numerator</b>	
Net loss attributable to common stockholders	\$ (18,479)
<b>Denominator</b>	
Weighted-average common stock outstanding	17,067,346
Less: weighted-average common shares subject to repurchase	(318,801)
Weighted-average common shares used to compute basic and diluted net loss per share	16,748,545
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.10)

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

	<b>Year Ended December 31, 2018</b>
Convertible preferred stock	126,490,496
Convertible preferred stock warrants	2,152,939
Options to purchase common stock	26,265,227
Unvested early exercised common stock options	268,604
Conversion of convertible notes*	—

\* The conversion of the convertible notes into common stock is dependent on the outstanding loan balance including accrued interest and the conversion stock per share price at the date of Qualified Equity Financing, Change of Control, Liquidation, or Prepayment Conversion (see Note 6). These factors are not estimable and the number of common stock is not determinable.

### 13. Segment Information

The chief operating decision maker for the Company is the Chief Executive Officer. The Company's Chief Executive Officer reviews financial information presented on a consolidated basis, accompanied by information about revenue by geographic region, for purposes of allocating resources and evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results or plans for levels or components below the consolidated unit level. Accordingly, the Company has determined that it has a single reportable and operating segment structure. The Company's Chief Executive Officer evaluates performance based primarily on revenue in the geographic locations in which the Company operates.

Revenue by geographic area is based on the billing address of the customer. The following table sets forth our revenue by geographic area (in thousands):

	<b>Year Ended December 31, 2018</b>
Europe, Middle-East and Africa ("EMEA")	\$ 16,175
Asia Pacific	3,115
Other International	151
United States	563
<b>Total</b>	<b>\$ 20,004</b>

Long-lived assets by geographic area are based on physical location of those assets. The following table sets forth our long-lived assets by geographic area (in thousands):

	<b>December 31, 2018</b>
United States	\$ 322
EMEA	37
Asia Pacific	16
<b>Total</b>	<b>\$ 375</b>

#### **14. Employee Benefit Plan**

Effective October 1997, the Company implemented a retirement savings plan (the “Savings Plan”) which is intended to qualify as a deferred savings plan under Section 401(k) of the Internal Revenue Code. Participants are allowed to contribute up to 100% of the total compensation, not to exceed the amount allowed by the applicable statutory prescribed limit. There have been no contributions made to the Savings Plan by the Company since inception.

#### **15. Related Parties**

Since October 2013, the Company has received services from the chairman of a subsidiary of the Company. During 2014, this person served as Interim CEO and was appointed to the Board of Directors of the Company. Amounts paid related to consulting services for the year ended December 31, 2018 was \$0.1 million.

See Note 6 for details regarding the Company’s Second Lien Loan and Security Agreement with Boston Scientific Corporation.

#### **16. Subsequent Events**

In January 2019, the Company borrowed \$6.0 million pursuant to the Second Lien Loan and Security Agreement with Boston Scientific Corporation. All Secured Convertible Promissory Notes converted into shares of Series G-1 convertible preferred stock.

In April 2019, the Company issued 30,303,026 shares of Series G-1 convertible preferred stock at a price of \$1.32 per share for cash proceeds of approximately \$40.0 million. Additionally, the Company issued 19,039,350 shares of Series G-1 convertible preferred stock at a price of \$1.32 per share upon the conversion and termination of \$25.1 million of convertible promissory notes and accrued interest with Boston Scientific Corporation. The liquidation right of Series G-1 convertible preferred stock is senior to Series F-1. If the Series G-1 shares are converted to common stock in connection with an IPO and the offering price in the IPO is less than 1.15 times the conversion price immediately prior to the IPO for the Series G-1 shares, the conversion price for the Series G-1 shares will be adjusted such that, upon the closing of the IPO, each share of Series G-1 stock will convert to common stock at 1.15 times the conversion price immediately prior to the IPO.

In May 2019, the Company elected to extend the interest only period for the \$15.0 million outstanding under the Loan and Security Agreement with Oxford Finance LLC through March 2020 and the maturity date to May 2021.

In November 2019, the Company renewed its lease for the headquarters location in Redwood City, California for an additional five years commencing in August 2020 and expiring in July 2025. The monthly base rent during the renewed term will be \$0.1 million and is subject to an annual increase of 3.5%.

Management has evaluated all transactions and events through December 13, 2019, the date which these consolidated financial statements were available to be issued.

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Through and including \_\_\_\_\_, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

**Shares**



**Pulmonx Corporation**

**Common Stock**

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**PROSPECTUS**

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**BofA Securities**

**Morgan Stanley**

**Stifel**

**Wells Fargo Securities**

**Canaccord Genuity**

, 2020

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**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth all costs and expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the FINRA filing fee and the exchange listing fee.

	<b>Amount to be Paid</b>	
SEC Registration Fee	\$	*
FINRA filing fee		*
Exchange listing fee		*
Printing and engraving		*
Legal fees and expenses		*
Accounting fees and expenses		*
Transfer agent and registrar fees		*
Miscellaneous fees and expenses		*
<b>Total</b>	<b>\$</b>	<b>*</b>

\* To be completed by amendment.

**Item 14. Indemnification of Directors and Officers.**

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct, or knowingly violated a law, authorized the payment of a dividend, or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit, or proceeding to which such person is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue, or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the Delaware General Corporation Law, our amended and restated certificate of incorporation and amended and restated bylaws in effect upon the completion of this offering provide that: (1) we are required to indemnify our directors to the fullest extent permitted by the Delaware General Corporation Law; (2) we may, in our discretion, indemnify our officers, employees, and agents as set forth in the Delaware General Corporation Law; (3) we are required, upon satisfaction of certain conditions, to advance all expenses incurred by our directors in

connection with certain legal proceedings; (4) the rights conferred in the bylaws are not exclusive; and (5) we are authorized to enter into indemnification agreements with our directors, officers, employees, and agents.

Our policy is to enter into agreements with our directors that require us to indemnify them against expenses, judgments, fines, settlements, and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. These indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. At present, no litigation or proceeding is pending that involves any of our directors regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

In addition, the underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification by the underwriters, under certain conditions, of us and our officers and directors for certain liabilities arising under the Securities Act. Our amended and restated investors rights agreement with certain stockholders also provides for cross-indemnification in connection with the registration of our common stock on behalf of such investors.

#### **Item 15. Recent Sales of Unregistered Securities.**

The following list sets forth information regarding all unregistered securities issued by us since January 1, 2017 through the date of the prospectus that is a part of this registration statement. 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 SEC, under which exemption from registration was claimed.

##### ***Issuances of Common Stock and Options to Purchase Common Stock***

From January 1, 2017 through December 31, 2019, we granted under our 2010 Stock Plan options to purchase an aggregate of 16,315,101 shares of our common stock to employees, consultants, and directors, having exercise prices ranging from \$0.13 to \$0.50 per share. Of these, options to purchase an aggregate of 388,972 shares have been cancelled without being exercised. From January 1, 2017 through December 31, 2019, an aggregate of 1,229,000 shares of our common stock were issued upon the exercise of stock options under the 2000 Stock Plan, at exercise prices between \$0.06 and \$0.15 per share, for aggregate proceeds of approximately \$0.1 million and an aggregate of 4,168,098 shares of our common stock were issued upon the exercise of stock options under the 2010 Stock Plan, at exercise prices between \$0.13 and \$0.24 per share, for aggregate proceeds of approximately \$0.6 million.

The offers, sales, and issuances of the securities described in the preceding paragraph were deemed to be exempt from registration either under Rule 701 promulgated under the Securities Act (Rule 701) in that the transactions were under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2). The recipients of such securities were our employees, directors, or consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions.

## Issuances of Preferred Stock and Warrants

These securities were issued pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, in reliance on the recipient's status as an "accredited investor" as defined in Rule 501(a) of Regulation D.

In January 2017, we issued and sold an aggregate of 7,575,757 shares of Series F-1 Preferred Stock to one accredited investor at \$1.32 per share for an aggregate consideration of approximately \$9,999,999.24.

In April 2019, we issued and sold an aggregate of 49,342,376 shares of Series G-1 Preferred Stock to 18 accredited investors at \$1.32 per share for an aggregate consideration of approximately \$65,131,936.32.

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.

<b>Exhibit Number</b>	<b>Description of Document</b>
1.1†	Form of Underwriting Agreement.
3.1*	Amended and Restated Certificate of Incorporation of Pulmonx Corporation, as currently in effect.
3.2†	Form of Amended and Restated Certificate of Incorporation of Pulmonx Corporation, to be effective upon the completion of this offering.
3.3*	Amended and Restated Bylaws of Pulmonx Corporation, as currently in effect.
3.4†	Form of Amended and Restated Bylaws of Pulmonx Corporation, to be effective upon the completion of this offering.
4.1†	Form of common stock certificate of Pulmonx Corporation.
4.2*	Amended and Restated Investors' Rights Agreement by and among Pulmonx Corporation and certain of its stockholders, dated April 16, 2019.
5.1†	Opinion of Cooley LLP.
10.1*+	2010 Stock Plan, as amended to date.
10.2*+	Forms of Notice of Stock Option Grant, Option Agreement, and Exercise Notice under 2010 Stock Plan.
10.3+†	2020 Equity Incentive Plan, as amended to date.
10.4+†	Forms of Option Agreement, Notice of Stock Option Grant, and Exercise Notices under 2020 Equity Incentive Plan.
10.5+†	Form of Restricted Stock Unit Award Agreement under 2020 Equity Incentive Plan.
10.6+†	2020 Employee Stock Purchase Plan.
10.7†	Form of Indemnification Agreement by and between Pulmonx Corporation and each of its directors and executive officers.

- 10.8\*+ Executive Employment Agreement, by and between Pulmonx Corporation and Glendon E. French, dated December 10, 2014.
- 10.9\*+ Offer Letter Agreement, by and between Pulmonx Corporation and Geoffrey Beran Rose, dated December 11, 2014.
- 10.10\*+ Offer Letter Agreement, by and between Pulmonx Corporation and Derrick Sung, Ph.D., dated March 12, 2019.
- 10.11\*+ Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated October 1, 2013.
- 10.12\*+ Amendment to Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated March 1, 2014.
- 10.13\*+ Second Amendment to Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated July 14, 2014.
- 10.14\*+ Third Amendment to Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated April 27, 2015.
- 10.15\*+ Appointment Letter, by and between PulmonX International Sàrl and Oern R. Stuge, dated December 18, 2013.
- 10.16\* Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated September 4, 2009.
- 10.17\* First Amendment to Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated October 3, 2014.
- 10.18\* Second Amendment to Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated November 7, 2019.
- 10.19\* Loan and Security Agreement, by and between Pulmonx Corporation, those certain Lenders party thereto and Oxford Finance LLC, dated August 28, 2014.
- 10.20\* First Amendment to Loan and Security Agreement, by and between Pulmonx Corporation, those certain Lenders party thereto and Oxford Finance LLC, dated May 15, 2017.
- 10.21\* Second Amendment to Loan and Security Agreement, by and between Pulmonx Corporation, those certain Lenders party thereto and Oxford Finance LLC, dated May 14, 2018.
- 10.22\* Third Amendment to Loan and Security Agreement, by and between Pulmonx Corporation, those certain Lenders party thereto and Oxford Finance LLC, dated May 22, 2018.
- 10.23 Second Lien Loan and Security Agreement, by and between Pulmonx Corporation and Boston Scientific Corporation, dated May 15, 2017.
- 21.1\* List of Subsidiaries of Registrant.
- 23.1† Consent of Cooley LLP (included in Exhibit 5.1).
- 23.2† Consent of BDO USA, LLP, independent registered public accounting firm.
- 24.1† Power of Attorney (included on signature page hereto).

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+ Indicates management contract or compensatory plan.  
† To be filed by amendment.  
\* Previously filed

**(b) Financial Statement Schedules**

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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 SEC 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 registrant 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.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Redwood City, State of California, on the \_\_\_\_\_ day of \_\_\_\_\_, 2020.

PULMONX CORPORATION

By: \_\_\_\_\_

Glendon E. French  
*President, Chief Executive Officer and Director*

**POWER OF ATTORNEY**

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Glendon E. French and Derrick Sung, and each of them, his or her true and lawful agent, proxy, and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to (1) act on, sign, and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (2) act on, sign, and file such certificates, instruments, agreements, and other documents as may be necessary or appropriate in connection therewith, (3) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (4) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy, and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Glendon E. French	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2020
_____ Derrick Sung, Ph.D.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2020
_____ Charles Chon	Director	, 2020
_____ Richard Ferrari	Director	, 2020
_____ Daniel Florin	Director	, 2020
_____ Staffan Lindstrand	Director	, 2020
_____ Michael Matly, M.D.	Director	, 2020
_____ Dana G. Mead, Jr.	Director	, 2020
_____ Rodney Perkins, M.D.	Director	, 2020
_____ Stephen Salmon	Director	, 2020
_____ Oern Stuge, M.D.	Director	, 2020

THIS AGREEMENT AND THE RIGHTS AND OBLIGATIONS EVIDENCED HEREBY ARE SUBORDINATE IN THE MANNER AND TO THE EXTENT SET FORTH IN THAT CERTAIN SUBORDINATION AGREEMENT, DATED AS OF THE DATE HEREOF (AS AMENDED, THE "SUBORDINATION AGREEMENT"), AMONG OXFORD FINANCE LLC ("OXFORD"), PULMONX CORPORATION ("BORROWER"), AND BOSTON SCIENTIFIC CORPORATION (THE "LENDER"), TO (A) THE OBLIGATIONS OWED BY BORROWER AND OTHER OBLIGORS PURSUANT TO THAT CERTAIN LOAN AND SECURITY AGREEMENT, DATED AS OF AUGUST 28, 2014, AMONG BORROWER, OXFORD, AS A LENDER AND THE COLLATERAL AGENT THEREUNDER, AND THE OTHER LENDERS PARTY THERETO FROM TIME TO TIME, AS SUCH LOAN AND SECURITY AGREEMENT HAS BEEN AND HEREAFTER MAY BE AMENDED, RESTATED SUPPLEMENTED OR OTHERWISE MODIFIED FROM TIME TO TIME IN ACCORDANCE WITH THE TERMS OF THE SUBORDINATION AGREEMENT (THE "OXFORD LOAN AGREEMENT"), AND (B) OBLIGATIONS REFINANCING THE OBLIGATIONS UNDER THE OXFORD LOAN AGREEMENT AS CONTEMPLATED BY THE SUBORDINATION AGREEMENT.

## SECOND LIEN LOAN AND SECURITY AGREEMENT

THIS SECOND LIEN LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this "Agreement") dated as of May 15, 2017 (the "Effective Date") between BOSTON SCIENTIFIC CORPORATION, a Delaware corporation with an office located at 300 Boston Scientific Way, Marlborough, MA 01572 (the "Lender"), and PULMONX CORPORATION, a Delaware corporation with offices located at 700 Chesapeake Drive, Redwood City, CA 94063 ("Borrower"), provides the terms on which the Lender shall lend to Borrower and Borrower shall repay the Lender. The parties agree as follows:

### 1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "Dollars" or "\$" are United States Dollars, unless otherwise noted.

### 2. LOANS AND TERMS OF PAYMENT

2.1 **Promise to Pay.** Borrower hereby unconditionally promises to pay the Lender the outstanding principal amount of all Term Loans advanced to Borrower by the Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

#### 2.2 **Term Loans.**

(a) Availability. Subject to the terms and conditions of this Agreement, the Lender agrees to make one or more term loans to Borrower during the period beginning on the Effective Date and ending on the Maturity Date in an aggregate amount not to exceed Thirty Million Dollars (\$30,000,000.00) (such term loans are hereinafter referred to singly as a "Term

**Loan**", and collectively as the "**Term Loans**"). Each Term Loan shall be in an aggregate minimum amount of \$3,000,000 and integral multiples of \$500,000 in excess of that amount. After repayment, no Term Loan may be re-borrowed.

(b) Repayment. All principal and accrued and unpaid interest with respect to each Term Loan that has not been converted to Conversion Stock or exchanged for an Exchange Note is due and payable in full on the Maturity Date. The Term Loans may only be prepaid in accordance with Section 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to the Lender an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, plus (ii) all other Obligations that are due and payable, including Lender Expenses and interest at the Default Rate with respect to any past due amounts.

(d) Permitted Prepayment of Term Loans. Subject to Lender's conversion rights pursuant to Section 2.7(d), Borrower shall have the option to prepay all of the Term Loans, at any time, provided Borrower (i) provides written notice (the "**Prepayment Notice**") to the Lender of its election to prepay the Term Loans at least fifteen (15) days prior to such prepayment (or such shorter period of time as acceptable to the Lender in its reasonable discretion), and (ii) pays to the Lender on the date of such prepayment an amount equal to the sum of (A) all outstanding principal of the Term Loans plus all accrued and unpaid interest thereon through the prepayment date, plus (B) all other Obligations that are due and payable, including interest at the Default Rate with respect to any past due amounts.

### **2.3 Payment of Interest on the Credit Extensions.**

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans drawn prior to June 30, 2018 (the "**Initial Term Loans**") shall accrue no interest from the date of such Term Loan through and including June 30, 2018. Beginning on July 1, 2018, all Initial Term Loans, and all Term Loans drawn on or after July 1, 2018, shall accrue interest at a fixed per annum rate (which rate shall be fixed for the duration of the applicable Term Loan) equal to the Basic Rate. Interest shall accrue on each Term Loan commencing on, and including, the later of July 1, 2018 and the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is converted to Conversion Stock, exchanged for an Exchange Note, or paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of the Lender.



(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year consisting of twelve (12) months of thirty (30) days, and shall be compounded annually.

(d) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the Lender at its office in immediately available funds on the date specified herein. Payments of principal and/or interest received after 2:00 p.m. Eastern Time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

#### **2.4 Secured Convertible Promissory Notes.**

(a) Form of Note. Each Term Loan shall be evidenced by a separate Secured Convertible Promissory Note in the form attached as Exhibit C hereto (each a “**Secured Promissory Note**”), and shall be repayable, convertible and exchangeable as set forth in this Agreement and such Secured Promissory Note.

(b) Replacement Notes. Upon receipt of an affidavit of an officer of the Lender as to the loss, theft, destruction, or mutilation of any Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

**2.5 Expenses**. Borrower and the Lender shall each pay all costs and expenses (including attorneys’ fees) that it incurs with respect to preparing and negotiating and, except in connection with defending or enforcing the Loan Documents, amending and administering the Loan Documents incurred through and after the Effective Date. Borrower shall pay to the Lender all Lender Expenses that it incurs with respect to defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with (a) appeals or Insolvency Proceedings and (b) amending and administering the Loan Documents in connection with defending and enforcing the Loan Documents) incurred through and after the Effective Date, when due.

**2.6 Withholding**. Payments received by the Lender from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lender, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, the Lender receives a net sum equal to the sum which it would have received had no withholding

or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lender with proof reasonably satisfactory to the Lender indicating that Borrower has made such withholding payment; *provided, however*, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement. The Lender shall deliver to Borrower, on or prior to the date on which such the Lender becomes a party to this Agreement (and from time to time thereafter upon the reasonable request of Borrower), a properly completed and duly executed original of IRS Form W-9 or any successor form, certifying that the Lender is exempt from United States federal backup withholding tax.

## 2.7 Conversion or Exchange Upon Qualified Events.

### (a) Definitions.

(i) “**Conversion Date**” shall be the date upon which the applicable Qualified Event is consummated.

(ii) “**Conversion Stock**” means (A) with respect to a Qualified Equity Financing, the preferred stock issued in such Qualified Equity Financing or (B) with respect to a Change of Control, Liquidation or Prepayment Conversion, at the Lender’s option, either (1) the Series F-1 Preferred Shares or, if the Series F-1 Preferred Shares are not the most senior series of preferred stock of Borrower then issued and outstanding (2) the most senior series of preferred stock of Borrower then issued and outstanding.

(iii) “**Conversion Stock Per Share Price**” means (A) with respect to a Qualified Equity Financing, the lowest price per share of Conversion Stock paid by any investor in such Qualified Equity Financing, (B) with respect to a Change of Control or Liquidation, the total amount (including the maximum potential value of any contingent payments) distributed, paid or to be paid to the stockholders of Borrower on account of the stock held by them in connection with such Change of Control or Liquidation, divided by the fully-diluted share count of Borrower on the Conversion Date (prior to inclusion of the Conversion Stock) or (C) with respect to a Prepayment Conversion, \$230,000,000 divided by the fully-diluted share count of Borrower on the Conversion Date (prior to inclusion of the Conversion Stock). For the purposes of the foregoing, “fully diluted share count” shall mean all outstanding shares of capital stock of the Company on an as converted to common stock basis, assuming the full exercise of all outstanding stock options and warrants but excluding, for any conversion in connection with a Change of Control or Liquidation, (1) shares of capital stock reserved for future grant under Borrower’s equity incentive plan, (2) shares of capital stock subject to unvested stock options that do not vest as part of the Change of Control or Liquidation and (3) out-of-the-money stock options and warrants.

(iv) “**Exchange Note**” means promissory notes of Borrower convertible into the Company’s preferred stock issued in a Qualified Debt Financing.

(v) “**Outstanding Balance**” means, with respect to a Secured Promissory Note converted or exchanged in a Qualified Event, the outstanding, unconverted, principal balance of such Secured Promissory Note as of the Conversion Date, plus all accrued but unpaid interest thereon as of the Conversion Date.

(vi) “**Prepayment Conversion**” means an optional conversion by Lender within thirty (30) days of Lender’s receipt of the Prepayment Notice.

(vii) “**Qualified Debt Financing**” means any issuance by Borrower of Exchange Notes that raises aggregate proceeds of at least \$5,000,000, but shall not include the conversion of the Secured Promissory Notes issued hereunder.

(viii) “**Qualified Equity Financing**” means any issuance by Borrower of Series F-1 Preferred Shares or Series G-1 Preferred Shares that raises aggregate proceeds, less all costs and expenses of Borrower incurred in connection with such Qualified Equity Financing, of at least \$5,000,000, but shall not include the Secured Promissory Notes issued hereunder.

(ix) “**Qualified Event**” means a Qualified Debt Financing, Qualified Equity Financing, Change of Control, Liquidation, or Prepayment Conversion, as applicable.

(x) “**Series F-1 Preferred Shares**” means shares of preferred stock, par value \$0.001 per share, of Borrower designated as Series F-1 Preferred Stock.

(xi) “**Series G-1 Preferred Shares**” means shares of any other series of preferred stock of Borrower that is *pari passu* or senior to the Series F-1 Preferred Shares, whether or not designated as “Series G-1 Preferred Stock” and having such other customary terms reasonably acceptable to the Lender.

(b) Conversion Upon Qualified Equity Financing, Change in Control or Liquidation. If, after the Effective Date and prior to repayment or conversion of all outstanding principal and interest on any Secured Promissory Notes, Borrower completes any Qualified Equity Financing or any Change of Control or Liquidation occurs, the Lender may, at its option, cause one or more Secured Promissory Notes to be simultaneously converted into a number of shares of Conversion Stock equal to (i) the Outstanding Balance divided by (ii) the applicable Conversion Stock Per Share Price. The Lender’s exercise of its conversion rights under this section shall be deemed to satisfy its obligation to pay the principal amount of Term Loans, in respect of which such conversion right is being exercised as of the date of the applicable Conversion Date.

(c) Exchange Upon Qualified Debt Financing. If, after the Effective Date, and prior to repayment or conversion of all outstanding principal and interest on any Secured Promissory Notes, Borrower completes any Qualified Debt Financing, the Lender may, at its option, cause one or more Secured Promissory Notes to be simultaneously exchanged for an Exchange Note issued in such Qualified Debt Financing, and the initial principal balance of such Exchange Note shall be the Outstanding Balance. The Lender’s exercise of its exchange rights under this section shall be deemed to satisfy its obligation to pay the principal amount of Term Loans, in respect of which such exchange right is being exercised as of the date of the applicable Conversion Date.

(d) Prepayment Conversion. If, after the Effective Date and prior to repayment or conversion of all outstanding principal and interest on any Secured Promissory Notes, Borrower delivers a Prepayment Notice to Lender, the Lender may, at its option, cause one or more Secured Promissory Notes to be converted into a number of shares of Conversion Stock equal to (i) the Outstanding Balance divided by (ii) the applicable Conversion Stock Per Share Price. The Lender's exercise of its conversion rights under this section shall be deemed to satisfy its obligation to pay the principal amount of Term Loans, in respect of which such conversion right is being exercised as of the date of the applicable Conversion Date.

(e) Conversion/Exchange Procedures.

(i) If Borrower intends to consummate a Qualified Event (other than a Prepayment Conversion under Section 2.2(d)), Borrower shall deliver to the Lender written notice of all material terms (including the proposed date of consummation) of, and then current documentation with respect to, such Qualified Event as soon as reasonably practicable and, in any event, at least fifteen (15) days prior to the proposed date of consummation of such Qualified Event. If the Lender desires to convert or exchange one or more Secured Promissory Note(s) pursuant to Sections 2.7(b) or (c) in connection with such Qualified Event, Lender shall deliver written notice to Borrower at least three (3) Business Days prior to the proposed date of consummation of such Qualified Event (provided, that, in the case of a Change of Control or Liquidation, Borrower may require Lender to deliver such notice a reasonable time more than three (3) Business Days prior to such consummation in order to comply with its obligations under the definitive agreement for such Change of Control or Liquidation), which notice shall set forth the date and principal amount of each Secured Promissory Note to be converted or exchanged in such Qualified Event. If the Lender desires to convert or exchange one or more Secured Promissory Note(s) pursuant to Section 2.7(d), in connection with a Prepayment Conversion, Lender shall deliver written notice to Borrower at least three (3) Business Days prior to the proposed date of consummation of such Prepayment Conversion.

(ii) On the Conversion Date, (A) the holder of a Secured Promissory Note to be converted or exchanged in such Qualified Event will surrender such Secured Promissory Note(s), duly endorsed, to Borrower in the manner and at the place reasonably designated by Borrower and (B) Borrower will issue to such holder the Conversion Stock or Exchange Note, as applicable. Borrower shall be deemed to have fully and indefeasibly performed all of its obligations under each Secured Promissory Note so converted or exchanged, and each holder of each Secured Promissory Note so converted or exchanged shall immediately upon such conversion or exchange be, for all purposes, the record holder of such Conversion Stock or Exchange Note, as applicable.

(iii) If, within six (6) months following a Prepayment Conversion (the "**Lookback Period**"), the Company consummates a Qualified Equity Financing (a "**Post Conversion Equity Financing**"), Lender may, at its option exchange the Conversion Stock issued to Lender in connection with the Prepayment Conversion for the preferred stock issued in such Post Conversion Equity Financing (such right, the "**Equity Exchange Right**"); provided, however, that each of Lender's Equity Exchange Right shall immediately terminate and the Lookback Period shall be reduced to zero (0) days immediately following (a) the occurrence of any Change of Control and/or Liquidation, and (b) the occurrence of any Post Conversion Equity Financing. If Borrower

intends to consummate a Post Conversion Equity Financing, Borrower shall deliver to the Lender written notice of all material terms (including the proposed date of consummation) of, and documentation with respect to, such Post Conversion Equity Financing as soon as reasonably practicable and, in any event, at least fifteen (15) days prior to the proposed date of consummation of such Post Conversion Equity Financing. If the Lender desires to exercise its Equity Exchange Right, Lender shall deliver written notice (the “**Exchange Notice**”) to Borrower at least three (3) Business Days prior to the initial date of termination for the Lookback Period. If Lender provides the Exchange Notice, effective on the consummation of the Post Conversion Equity Financing, (a) each share of Conversion Stock issued to Lender and/or its affiliates, successors and assigns in connection with the Prepayment Conversion shall be automatically exchanged for the preferred stock issued in such Post Conversion Equity Financing at a ratio obtained by dividing the Conversion Stock Per Share Price in the Prepayment Conversion by the lowest price per share of preferred stock paid by any investor in such Post Conversion Equity Financing, and (b) each of Lender’s Lookback Exchange Rights shall immediately terminate and the Lookback Period shall be reduced to zero (0) days.

(iv) If, within the Lookback Period, Borrower consummates a Change in Control or Liquidation (a “**Post Conversion Change in Control**”), Lender may, at its option, exchange the Conversion Stock issued to Lender in connection with the Prepayment Conversion for the Conversion Stock that Lender would have received had the Secured Promissory Note(s) that were converted in the Prepayment Conversion been converted pursuant to Section 2.7(b) instead (such right, the “**Change in Control Exchange Right**”); provided, however, that each of Lender’s Lookback Exchange Rights shall immediately terminate and the Lookback Period shall be reduced to zero (0) days immediately following the occurrence of such Change of Control and/or Liquidation. If Lender desires to exercise its Change in Control Exchange Right, (a) Borrower and Lender shall follow the Conversion/Exchange Procedures set forth in Section 2.7(e)(i), (b) effective immediately prior to the closing of the Post Conversion Change in Control, all Conversion Stock issued to Lender and/or its affiliates, successors and assigns in connection with the Prepayment Conversion shall be automatically exchanged for the number of shares of Conversion Stock that Lender would have received had the Secured Promissory Note(s) that were converted in the Prepayment Conversion been converted pursuant to Section 2.7(b) instead, and (c) each of Lender’s Lookback Exchange Rights shall immediately terminate.

(v) Borrower shall not issue fractional shares upon conversion of any Secured Promissory Note or exchange of Conversion Stock. In lieu of issuing fractional shares, Borrower will pay to the holder of a Secured Promissory Note converted in a Qualified Event a cash amount equal the amount designated for conversion but not so converted. In lieu of issuing fractional shares in a Post Conversion Equity Financing, Lender will retain – and not exchange – a number of shares of Conversion Stock such that only a whole number of shares of preferred stock are issued to Lender in any Post Conversion Equity Financing.

(f) Reservation of Shares. Borrower will take all such actions reasonably necessary to authorize a sufficient number of shares of preferred stock or other applicable capital stock, as applicable, to allow for the conversion of the maximum amount of Secured Promissory Notes or exchange of Conversion Stock issuable hereunder into preferred stock or other capital stock, as applicable prior to the conversion of such Secured Promissory Notes or exchange of

Conversion Stock; provided, however, that nothing herein will be deemed to require Borrower to authorize the issuance of preferred stock solely for purposes of converting Secured Promissory Notes unless Borrower is authorizing and issuing preferred stock in connection with a Qualified Equity Financing or Post Conversion Equity Financing or delivering a Prepayment Notice.

(g) Investors Rights. The conversion or exchange of any Secured Promissory Note pursuant to this Section 7.7 is subject to Borrower providing Lender such rights, benefits and preferences (including representations and warranties, rights of first refusal, registration rights, warrant coverage and legal opinion) as generally enjoyed by all investors in the Qualified Equity Financing or Post Conversion Equity Financing, including pursuant to the Stockholder Documents and Lender executing all financing documents executed by other investors in the Qualified Equity Financing or Post Conversion Equity Financing.

### **3. CONDITIONS OF LOANS**

**3.1 Conditions Precedent to Initial Credit Extension.** The Lender's obligation to make the first Term Loan is subject to the condition precedent that the Lender shall consent to or shall have received, in form and substance satisfactory to the Lender, such documents, and completion of such other matters, as the Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower;

(b) good standing certificates or equivalent of Borrower certified by the Secretary of State of Borrower's jurisdiction of organization, as of a date no earlier than thirty (30) days prior to the Effective Date;

(c) a completed Perfection Certificate for Borrower and each of its Subsidiaries;

(d) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as the Lender shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(e) trademark, patent and copyright security agreements, executed by Borrower in favor of the Lender, as the Lender may reasonably request (the "**IP Security Agreements**"); and

(f) such other documents and agreements as the Lender may reasonably request to grant and perfect its security interest in the Collateral.

**3.2 Conditions Precedent to all Credit Extensions.** The obligation of the Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by the Lender of an executed Borrowing Request in the form of Exhibit B attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the Funding Date of each Credit Extension; *provided, however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and *provided, further* that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; *provided, however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in the Lender's sole but reasonable discretion, there has not been any Material Adverse Change; and

(d) receipt of a duly executed original Secured Promissory Note, in form and content reasonably acceptable to the Lender, and in favor of the Lender in the amount of such Credit Extension.

**3.3 Covenant to Deliver.** Borrower agrees to deliver to the Lender each item required to be delivered to the Lender under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by the Lender of any such item shall not constitute a waiver by the Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in the Lender's sole discretion.

**3.4 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall deliver a Borrowing Request executed by a Responsible Officer or his or her designee to the Lender (which Borrowing Request shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 p.m. Eastern time five (5) Business Days prior to the date the Term Loan is to be made. On the Funding Date, the Lender shall transfer an amount equal to such Term Loan pursuant to the Borrowing Request.

#### **4. CREATION OF SECURITY INTEREST**

**4.1 Grant of Security Interest.** Borrower hereby grants the Lender, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to the Lender, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected

security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to the Lender's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower shall promptly notify the Lender in a writing signed by Borrower of the general details thereof (and further details as may be reasonably required by the Lender) and grant to the Lender in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to the Lender.

If this Agreement is terminated, the Lender's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) are repaid in full. Upon payment in full of the Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) and at such time as the Lender's obligation to make Credit Extensions has terminated, the Lender shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

Upon any sale, lease, transfer or other disposition of any item of Collateral of any Borrower or Guarantor not prohibited by the terms of the Loan Documents, or upon the effectiveness of any consent to the release of the security interest granted hereby in any Collateral pursuant to this Agreement, or upon the release of any Borrower or any Guarantor from its obligations under this Agreement or the applicable Guaranty, if any, in accordance with the terms of the Loan Documents, the Lender will, at such Borrower's or Guarantor's sole cost and expense, execute and deliver to such Borrower or Guarantor such documents as such Borrower or Guarantor shall reasonably request to evidence the release of such item of Collateral from the assignment and security interest granted hereby; *provided, however*, that (i) at the time of such request and such release no Event of Default shall have occurred and be continuing and (ii) such Borrower or Guarantor shall have delivered to the Lender, at least ten (10) Business Days' prior to the date of the proposed release, a written request for release describing the item of Collateral, together with a form of release for execution by the Lender, and such other information as the Lender may reasonably request.

**4.2 Authorization to File Financing Statements.** Borrower hereby authorizes the Lender to file financing statements or take any other action required to perfect the Lender's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect the Lender's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of the Lender under the Code. Such financing statements may indicate the Collateral as "all assets of the Debtor's" or words of similar effect, or as being of an equal or lesser scope, or with greater detail, all as reasonably determined by the Lender.

**4.3 Pledge of Share Collateral.** Borrower hereby pledges, assigns and grants to the Lender a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the



Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder and subject to the terms of the Subordination Agreement, the Lender may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of the Lender and cause new (as applicable) certificates representing such securities to be issued in the name of the Lender or its transferee. Subject to the terms of the Subordination Agreement Borrower will execute and deliver such documents, and take or cause to be taken such actions, as the Lender may reasonably request to perfect or continue the perfection of the Lender's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

## 5. **REPRESENTATIONS AND WARRANTIES**

Borrower represents and warrants to the Lender as follows:

**5.1 Due Organization, Authorization: Power and Authority.** Borrower and each of its Subsidiaries is duly existing and in good standing in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. The Borrower is a Registered Organization. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to the Lender a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) except as set forth in the Perfection Certificate, Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of the Lender. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one,

Borrower shall notify the Lender of such occurrence and provide the Lender with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of the Guarantors of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Guarantor's organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Guarantor, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

## **5.2 Collateral.**

(a) Borrower and each of the Guarantors have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00).

(c) All Inventory is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Each of Borrower's and its Subsidiaries' material Patents is valid and enforceable and no part of Borrower's or its Subsidiaries' material Intellectual Property has been judged invalid or unenforceable, in whole or in part, and (ii) to the best of Borrower's knowledge, no claim has been made that any part of the Intellectual Property or any practice by Borrower or its Subsidiaries violates the rights of any third party except to the extent such claim could not reasonably be expected to have a Material Adverse Change. Except as noted on the Perfection Certificates, neither Borrower nor any of the Guarantors is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Guarantor is the licensee that (i) prohibits or otherwise restricts Borrower or the Guarantors from granting a security interest in Borrower's or such Guarantor's interest in such material license or material agreement or any other property, or

(ii) for which a default under or termination of could interfere with the Lender's right to sell any Collateral. Borrower shall provide written notice to the Lender within ten (10) days of Borrower or any of its Subsidiaries entering into or becoming bound by any material license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

**5.3 Litigation.** Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.5 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars (\$250,000.00).

**5.4 No Material Deterioration in Financial Condition; Financial Statements.** All consolidated financial statements for Borrower and its Subsidiaries, delivered to the Lender fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries, subject only to normal year-end adjustments and the absence of footnotes. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries since the date of the most recent financial statements submitted to any Lender.

**5.5 Solvency.** Borrower and each of its Subsidiaries is Solvent.

**5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries have complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) a Blocked Person. None of Borrower, any of its Subsidiaries, or, to the knowledge of

Borrower, any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

**5.7 Use of Proceeds.** Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in the ordinary course of its business and in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

**5.8 Shares.** Borrower has full power and authority to create a lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable (to the extent such concepts exist under applicable law). To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

**5.9 Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to the Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to the Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading in light of the circumstances under which such statements were made (after giving effect to all supplements and updates thereto) (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon assumptions believed to be reasonable by the Borrower or such Subsidiary are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

**5.10 Definition of "Knowledge."** For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

## **6. AFFIRMATIVE COVENANTS**

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

**6.1 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices

as they exist at the Effective Date. Borrower must promptly notify the Lender and the Lenders of all returns, recoveries, disputes and claims that involve more than Two Hundred Fifty Thousand Dollars (\$250,000.00) individually or in the aggregate in any calendar year.

**6.2 Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested in good faith, and shall deliver to the Lender, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

**6.3 Insurance.** Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as the Lender may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to the Lender. All property policies of Borrower or any Guarantor shall have a lender's loss payable endorsement showing the Lender as lender loss payee and waive subrogation against the Lender, and all liability policies of the Borrower or any Guarantor shall show, or have endorsements showing, the Lender, as additional insured. The Lender shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Lender, that it will give the Lender thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At the Lender's reasonable request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Subject to the terms of the Subordination Agreement, proceeds payable under any policy of the Borrower or any Guarantor or covering the Collateral shall, at the Lender's option, be payable to the Lender on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to One Hundred Thousand Dollars (\$100,000.00) with respect to any loss, but not exceeding Two Hundred Fifty Thousand Dollars (\$250,000.00), in the aggregate for all losses under all casualty or property policies in any fiscal year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which the Lender has been granted a security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of the Lender, be payable to the Lender on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.3 or to pay any amount or furnish any required proof of payment to third persons, the Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.3, and take any action under the policies the Lender deems prudent.

**6.4 Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly notify the Lender in writing of material infringement by a third party of its Intellectual Property; (c) not

allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without the Lender's prior written consent; (d) promptly notify the Lender of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property; (e) notify the Lender no later than thirty (30) days after the last day of each quarter of (i) any patent, registered trademark or servicemark, registered copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, obtained by Borrower and its Subsidiaries and (ii) any applications for any patent or the registration of any trademark or servicemark made by Borrower or its Subsidiaries; and (f) promptly execute such intellectual property security agreements and other documents and take such other actions as the Lender shall reasonably request in its good faith business judgment to perfect and maintain a second priority perfected security interest in favor of the Lender, in each of Borrower's and its Subsidiaries' Intellectual Property.

**6.5 Notices of Litigation and Default.** Borrower will give prompt written notice to the Lender of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of One Hundred Thousand Dollars (\$100,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to the Lender of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

**6.6 Landlord Waivers; Bailee Waivers.** In the event that Borrower or any of the Guarantors, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, then Borrower or such Guarantor will first receive the written consent of the Lender.

**6.7 Creation/Acquisition of Subsidiaries.** In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to the Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by the Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to the Lender a perfected security interest in the Shares of each such newly created Subsidiary; *provided, however*, that solely in the circumstance in which Borrower creates or acquires a Foreign Subsidiary, (i) such Foreign Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents and grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary, and (ii) Borrower shall not be required to grant and pledge to the Lender a perfected security interest in more than sixty-five percent (65%) of the Shares of such Foreign Subsidiary.

**6.8 Further Assurances.** Execute any further instruments and take further action as the Lender reasonably requests to perfect or continue the Lender's Lien in the Collateral or to effect the purposes of this Agreement.

## **7. NEGATIVE COVENANTS**

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Lender:

**7.1 Changes in Business.** Borrower and the Guarantors shall not, without at least thirty (30) days' prior written notice to the Lender: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Five Hundred Thousand Dollars (\$500,000.00) in assets or property of Borrower or any of the Guarantors); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

**7.2 Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

**7.3 Encumbrance.** Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens.

## **8. EVENTS OF DEFAULT**

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

### **8.2 Covenant Default.**

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Taxes; Pensions), 6.3 (Insurance), 6.4 (Protection of Intellectual Property Rights), 6.5 (Notice of Litigation and Default), 6.6 (Landlord Waivers; Bailee Waivers), 6.7 (Creation/Acquisition of Subsidiaries) or 6.8 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure

the default within ten (10) days after the occurrence thereof; *provided, however*, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to any covenants set forth in subsection (a) above;

**8.3 Investor Abandonment; Priority of Security Interest.** The Lender determines in its good faith judgment, that (i) Borrower will not be able to satisfy the Obligations as they become due and payable, and (ii) none of Borrower's principal investors (defined as each investor that has designated a member of Borrower's Board of Directors) intends to fund such amounts as may be necessary to enable Borrower to satisfy the Obligations as they become due and payable;

**8.4 Attachment; Levy; Restraint on Business.**

(a) A notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency and is not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); *provided, however*, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) Any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

**8.5 Insolvency.** (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed) or (d) a Liquidation;

**8.6 Other Agreements.** (a) There is a default in the Oxford Loan Agreement resulting in the acceleration of the Indebtedness under such agreement or (b) there is a default in any other agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) or that could reasonably be expected to result in liability to Borrower or any of its Subsidiaries in an aggregate amount in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00);

**8.7 Judgments.** One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Two Hundred Fifty Thousand Dollars (\$250,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries



and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

**8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to the Lender or to induce the Lender to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

**8.9 Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with the Lender, or any creditor that has signed such an agreement with the Lender breaches any terms of such agreement;

**8.10 Guaranty.** (a) Except for any Guaranty permitted to be and in fact released or terminated by the Lender pursuant to this Agreement or the other Loan Documents, any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor; or (d) the liquidation, winding up, or termination of existence of any Guarantor;

**8.11 Governmental Approvals.** Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term and such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change;

**8.12 Lien Priority.** Except for Liens permitted to be and in fact released or terminated by the Lender pursuant to this Agreement or the other Loan Documents, any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement; or

**8.13 Change of Control.** A Change of Control occurs.

## **9. RIGHTS AND REMEDIES**

### **9.1 Rights and Remedies.**

(a) The Lender, each of its permitted successors and assigns, and each holder of a Secured Promissory Note (i) consents to and approves each and all of the provisions of the Subordination Agreement and (ii) acknowledges that the terms of this Agreement, each Secured Promissory Note, and each other Loan Document, and the rights and remedies (including the exercise thereof) of the Lender, its permitted successors and assigns, and the holders of Secured Promissory Notes set forth herein and therein, are subject to the terms of the Subordination Agreement.

(b) Upon the occurrence and during the continuance of an Event of Default, the Lender may, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by the Lender) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lender to advance money or extend credit for Borrower's benefit under this Agreement or any other Loan Document (but if an Event of Default described in Section 8.5 occurs, all Obligations, if any, of the Lender to advance money or extend credit for Borrower's benefit under this Agreement or under any other Loan Document shall be immediately terminated without any action by the Lender).

(c) Without limiting the rights of the Lender set forth in Section 9.1(b) above, upon the occurrence and during the continuance of an Event of Default, the Lender shall have the right, without notice or demand, to do any or all of the following:

- (i) foreclose upon and/or sell or otherwise liquidate, the Collateral;
- (ii) apply to the Obligations any amount held or controlled by the Lender owing to or for the credit or the account of Borrower; and/or
- (iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(d) Without limiting the rights of the Lender set forth in Sections 9.1(b) and (c) above, upon the occurrence and during the continuance of an Event of Default, the Lender shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that the Lender considers advisable, notify any Person owing Borrower money of the Lender's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if the Lender requests and make it available in a location as the Lender reasonably designates. The Lender may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants the Lender a license to enter and occupy any of its premises, without charge, to exercise any of the Lender's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. The Lender is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with the Lender's

exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to the Lender;

(iv) demand and receive possession of Borrower's Books;

(v) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vi) subject to clauses 9.1(b) and (c), exercise all rights and remedies available to the Lender and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

**9.2 Power of Attorney.** Borrower hereby irrevocably appoints the Lender as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Guarantor's name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Guarantor's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms the Lender determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of the Lender or a third party as the Code or any applicable law permits. Borrower hereby appoints the Lender as its lawful attorney-in-fact to sign Borrower's or any of its Guarantor's name on any documents necessary to perfect or continue the perfection of the Lender's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied in full and the Lender is under no further obligation to make Credit Extensions hereunder. The Lender's foregoing appointment as Borrower's or any of its Guarantor's attorney in fact, and all of the Lender's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been fully repaid and performed and the Lender's obligation to provide Credit Extensions terminates.

**9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.3 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, the Lender may obtain such insurance or make such payment, and all amounts so paid by the Lender are Obligations and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. The Lender will make reasonable efforts to provide Borrower with notice of the Lender obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by the Lender are

deemed an agreement to make similar payments in the future or the Lender's waiver of any Event of Default.

**9.4 Application of Payments and Proceeds.** Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by the Lender from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and the Lender on the other, the Lender shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as the Lender may deem advisable notwithstanding any previous application by the Lender, and (b) the net after tax proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lender Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to the Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct.

**9.5 Liability for Collateral.** So long as the Lender complies with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of the Lender, the Lender shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

**9.6 No Waiver; Remedies Cumulative.** Failure by the Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of the Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the Lender and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of the Lender under this Agreement and the other Loan Documents are cumulative. The Lender has all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by the Lender of one right or remedy is not an election, and the Lender's waiver of any Event of Default is not a continuing waiver. The Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

**9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by the Lender on which Borrower or any Subsidiary is liable.

**10. NOTICES**

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Either the Lender or Borrower may change its mailing address, email address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower: PULMONX CORPORATION  
700 Chesapeake Drive  
Redwood City, CA 94063  
Attn: Glen French  
Email: [Email Address Intentionally Omitted]

with a copy (which shall not constitute notice) to: COOLEY LLP  
3175 Hanover Street  
Palo Alto, CA 94304-1130  
Attn: Mark Weeks  
Email: [Email Address Intentionally Omitted]

If to the Lender: BOSTON SCIENTIFIC CORPORATION  
300 Boston Scientific Way  
Marlborough, MA 01572  
Attention: President – Endoscopy Division  
Email: [Email Address Intentionally Omitted]

with a copy (which shall not constitute notice) to: BOSTON SCIENTIFIC CORPORATION  
300 Boston Scientific Way  
Marlborough, MA 01572  
Attention: Chief Corporate Counsel  
Email: [Email Address Intentionally Omitted]

with a copy (which shall not constitute notice) to: FAEGRE BAKER DANIELS LLP  
1470 Walnut St. Suite 300  
Boulder, CO 80302  
Attn: John R. Marcil  
Email: [Email Address Intentionally Omitted]

## **11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER, AND JUDICIAL REFERENCE**

Except as otherwise expressly set forth in any Loan Document to the contrary, New York law governs the Loan Documents without regard to principles of conflicts of law. Borrower and the Lender each submit to the exclusive jurisdiction of the State and Federal courts in New York, New York; *provided, however*, that nothing in this Agreement shall be deemed to operate to preclude the Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of the Lender. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

**TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER AND THE LENDER EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

## **12. GENERAL PROVISIONS**

**12.1 Successors and Assigns.** This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without the Lender's prior written consent (which may be granted or withheld in the Lender's discretion, subject to Section 12.6). The Lender has the right to sell, transfer, assign, pledge, or negotiate (any such sale, transfer, assignment, or negotiation, a "**Lender Transfer**") all or any part of any Secured Promissory Note (including the Lender's rights and benefits under this Agreement and the other Loan Documents with respect thereto) to the extent the Lender would be permitted to sell, transfer, assign, pledge, or negotiate the underlying Conversion Stock pursuant to the terms of the Stockholder Documents; provided, however, so long as no Event of Default has occurred and is continuing, no Lender Transfer shall be permitted with respect to any such Secured Promissory Note, without Borrower's consent, to the extent the Borrower would be required to pay additional amounts pursuant to Section 2.6 of this Agreement to the applicable buyer, transferee, assignee, or other acquiror of such Secured Promissory Note than the Borrower would otherwise have had to pay to the Lender (or any of its applicable transferees, assignees, etc.).

**12.2 Indemnification.** Borrower agrees to indemnify, defend and hold the Lender and its directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing the Lender (each, an “**Indemnified Person**”) harmless against: (a) all obligations, demands, claims, and liabilities (collectively, “**Claims**”) asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lender Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between the Lender and Borrower (including reasonable attorneys’ fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person’s gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the reasonable fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by the Lender) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person’s gross negligence or willful misconduct.

**12.3 Time of Essence.** Time is of the essence for the performance of all Obligations in this Agreement.

**12.4 Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

**12.5 Correction of Loan Documents.** The Lender may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.

**12.6 Amendments in Writing; Integration.**

(a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower and the Lender.

(b) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to the subject matter hereof. All prior agreements, understandings, representations, warranties, and negotiations

between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

**12.7 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

**12.8 Survival.** All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify the Lender shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

**12.9 Intentionally Omitted.**

**12.10 Intentionally Omitted.**

**12.11 Cooperation of Borrower.** If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan to an assignee in accordance with Section 12.1, (ii) upon reasonable prior notice to Borrower (unless an Event of Default has occurred and is continuing) make Borrower's management available to meet with the Lender and prospective participants and assignees of a Term Loan (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist the Lender in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes the Lender to disclose to any prospective participant or assignee of a Term Loan, any and all information in the Lender's possession concerning Borrower and its financial affairs which has been delivered to the Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to the Lender by or on behalf of Borrower in connection with the Lender's credit evaluation of Borrower prior to entering into this Agreement.

**12.12 Tax Treatment.** Borrower and the Lender agree to treat all amounts borrowed pursuant to this Agreement (including, for the avoidance of doubt, all Term Loans and all Secured Promissory Notes issued pursuant to this Agreement) as debt for all U.S. federal and state income tax purposes, and, in accordance with Section 385(c) of the Internal Revenue Code of 1986, as amended (the "IRC"), such characterization shall be binding upon the Lender and Borrower (along with their successors and assigns) and they shall file their tax returns and reports consistent with such treatment.

### **13. DEFINITIONS**

**13.1 Definitions.** As used in this Agreement, the following terms have the following meanings:



“**Account**” is any “account” as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

“**Account Debtor**” is any “account debtor” as defined in the Code with such additions to such term as may hereafter be made.

“**Affiliate**” of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person’s senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person’s managers and members.

“**Agreement**” is defined in the preamble hereof.

“**Anti-Terrorism Laws**” are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

“**Basic Rate**” is, with respect to a Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to eight and ninety six hundredths of one percent (8.96%).

“**Blocked Person**” is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“**Borrower**” is defined in the preamble hereof.

“**Borrower’s Books**” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“**Borrowing Request**” is that certain form attached hereto as Exhibit B.

“**Business Day**” is any day that is not a Saturday, Sunday or a day on which the Federal Reserve Bank of New York is authorized or required by law or executive order to close or be closed.

“**Change of Control**” at any time, any Person or “group” (within the meaning of Rules 13d 3 and 13d 5 under the Securities Exchange Act of 1934, as amended, shall have acquired beneficial ownership of 50% or more on a fully diluted basis of the voting and/or economic interest in the capital stock of Borrower or shall have obtained the power (whether or not exercised) to elect a

majority of the members of the Board of Directors (or similar governing body) of Borrower, in each case, other than as a result of an Initial Public Offering.

“**Claims**” are defined in Section 12.2.

“**Code**” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; *provided, that*, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; *provided further*, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, the Lender’s Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term “Code” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

“**Collateral**” is any and all properties, rights and assets of Borrower described on Exhibit A.

“**Contingent Obligation**” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but “Contingent Obligation” does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

“**Copyrights**” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“**Credit Extension**” is any Term Loan extended by the Lender hereunder.

“**Dollars**” and “**\$**” is defined in Section 1.1.

“**Default Rate**” is defined in Section 2.3(b).

“**Dollars,**” “**dollars**” and “**\$**” each mean lawful money of the United States.

“**Effective Date**” is defined in the preamble of this Agreement.

**“Equipment”** is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

**“ERISA”** is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

**“Event of Default”** is defined in Section 8.

**“Financial Statements”** is defined in Section 5.6.

**“Foreign Subsidiary”** is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

**“Funding Date”** is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

**“GAAP”** is defined in Section 5.6.

**“General Intangibles”** are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

**“Governmental Approval”** is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

**“Governmental Authority”** is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

**“Guarantor”** is any Person providing a Guaranty in favor of the Lender. As of the Effective Date, there are no Guarantors.

**“Guaranty”** is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

**“Indebtedness”** is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

**“Indemnified Person”** is defined in Section 12.2.

**“Initial Public Offering”** means (a) the initial firm commitment underwritten offering of Borrower’s common stock pursuant to a registration statement under the Securities Act of 1933 filed with and declared effective by the Securities and Exchange Commission or (b) a “reverse merger” with an existing public company resulting in the direct or indirect parent of Borrower being a publicly-traded entity and the holders of stock of Borrower prior to such reverse merger becoming stockholders of such parent entity.

**“Initial Term Loans”** is defined in Section 2.3.

**“Insolvency Proceeding”** is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

**“Insolvent”** means not Solvent.

**“Intellectual Property”** means all of Borrower’s or any Subsidiary’s right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

**“Inventory”** is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or

possession or in transit and including any returned goods and any documents of title representing any of the above.

“**Investment**” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

“**IP Security Agreements**” is defined in Section 3.1.

“**IRC**” is defined in Section 12.12.

“**Lender**” is defined in the preamble hereof.

“**Lender Expenses**” are all audit fees and expenses, costs, and expenses (including reasonable and documented attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) of the Lender that are reimbursable pursuant to Section 2.5.

“**Lien**” is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“**Liquidation**” means the liquidation, winding up, or termination of existence of Borrower.

“**Loan Documents**” are, collectively, this Agreement, the Perfection Certificates, each Borrowing Request, the Subordination Agreement, all Secured Promissory Notes, all Guaranties, the IP Security Agreements, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lender in connection with this Agreement; all as amended, restated, or otherwise modified from time to time.

“**Lookback Exchange Rights**” means the Change in Control Exchange Right and the Equity Exchange Right.

“**Material Adverse Change**” is (a) a material impairment in the perfection or priority of the Lender’s Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

“**Maturity Date**” is May 13, 2022.

“**Obligations**” are all of Borrower’s obligations to pay when due any debts, principal, interest, Lenders’ Expenses, and other amounts Borrower owes the Lender now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lender, and the performance of Borrower’s duties under the Loan Documents.

“**OFAC**” is the U.S. Department of Treasury Office of Foreign Assets Control.

“**Operating Documents**” are, for any Person, such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

“**Oxford**” is defined in the legend above the preamble.

“**Oxford Loan Agreement**” is defined in the legend above the preamble.

“**Patents**” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

“**Perfection Certificate**” and “**Perfection Certificates**” is defined in Section 5.1.

“**Permitted Indebtedness**” is:

(a) Borrower’s Indebtedness to the Lender under this Agreement and the other Loan Documents;

(b) Borrower’s Indebtedness pursuant to the Oxford Loan Agreement and any other Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);

(c) Subordinated Debt;

(d) unsecured Indebtedness;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower’s business;

(g) Indebtedness constituting Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Indebtedness in an aggregate amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in respect of any cash management services, netting services, automatic clearinghouse arrangements, overdraft protections, employee credit card programs and other cash management and similar arrangements in the ordinary course of business and any guarantees thereof;

(i) guarantees by Borrower or any of its Subsidiaries in respect of (x) Indebtedness of Borrower or any of its Subsidiaries permitted hereunder and (y) obligations that do not constitute Indebtedness;

(j) Indebtedness in an aggregate amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) incurred by the Borrower or any of its Subsidiaries in respect of letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments issued or created in the ordinary course of business or consistent with past practice; and

(k) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (j) above, provided that in the case of secured Indebtedness, the principal amount thereof is not increased, the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be, and the terms are otherwise reasonably acceptable to the Lender.

**"Permitted Licenses"** are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, *provided, that*, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to the Lender and the Lenders and delivers to the Lender and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries.

**"Permitted Liens"** are:

(a) Liens pursuant to the Oxford Loan Agreement and Liens existing on the Effective Date and disclosed on the Perfection Certificates, arising under this Agreement and the other Loan Documents and arising under any Subordinated Debt;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the IRC, and the Treasury Regulations adopted thereunder;

(c) liens securing Indebtedness permitted under clause (e) of the definition of “**Permitted Indebtedness**,” provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Twenty Five Thousand Dollars (\$25,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers’ compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of business of Borrower and its Subsidiaries (or, if referring to another Person, in the ordinary course of such Person’s business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower’s business (or, if referring to another Person, in the ordinary course of such Person’s business), if the leases, subleases, licenses and sublicenses do not prohibit granting the Lender or any Lender a security interest therein;

(h) banker’s liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with deposit accounts or securities accounts of Borrower and its Subsidiaries held at such institutions solely to secure payment of fees and similar costs and expenses;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) Liens consisting of Permitted Licenses; and

(k) deposits to secure (A) the performance of bids, trade contracts, governmental contracts and leases (other than Indebtedness for borrowed money), statutory obligations, surety



and customs bonds, performance bonds and other obligations of a like nature (including those to secure health, safety and environmental obligations) and (B) stay and appeal bonds.

**“Person”** is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

**“Registered Organization”** is any “registered organization” as defined in the Code with such additions to such term as may hereafter be made.

**“Requirement of Law”** is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

**“Responsible Officer”** is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

**“Secured Promissory Note”** is defined in Section 2.4.

**“Shares”** is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower, in any Subsidiary; provided that **“Shares”** shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record directly by Borrower in a Foreign Subsidiary.

**“Solvent”** is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

**“Stockholder Documents”** means the Investors’ Rights Agreement, the Voting Agreement, the Right of First Refusal and Co-Sale Agreement and the Restated Certificate, as each such term is defined in the Stock Purchase Agreement.

**“Stock Purchase Agreement”** is defined in Section 5.1.

**“Subordinated Debt”** is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lender (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to the Lender entered into between the Lender, Borrower, and/or any of its Subsidiaries, and the other creditor or otherwise on terms acceptable to the Lender).

**“Subordination Agreement”** is defined in the legend above the preamble.

**“Subsidiary”** is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

“**Term Loan**” is defined in Section 2.2(a) hereof.

“**Trademarks**” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

*[Balance of Page Intentionally Left Blank]*

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

**BORROWER:**

PULMONX CORPORATION

By: /s/ Glen French  
Name: Glen French  
Title: President & CEO

**THE LENDER**

BOSTON SCIENTIFIC CORPORATION

By: /s/ Daniel J. Brennan  
Name: Daniel J. Brennan  
Title: Executive Vice President and Chief Financial Officer

*[Signature Page to Loan and Security Agreement]*

## EXHIBIT A

### Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles, Intellectual Property, commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) more than 65% of the total combined voting power of all classes of stock entitled to vote the shares of capital stock of any Foreign Subsidiary; (ii) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract; (iii) any "intent to use" trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise; and (iv) any equipment or other personal property subject to a Lien described in clause (a) or (c) of the definition of Permitted Liens if the granting of a Lien in such equipment or other personal property is prohibited by or would constitute a default under any agreement or document governing such property (but, in the case of (ii) and (iv), (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); *provided that* upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of the Lender hereunder and become part of the "Collateral."

**EXHIBIT B**

**Form of Borrowing Request**

[see attached]

## BORROWING REQUEST

\_\_\_\_\_, 20\_\_

The undersigned, being the duly elected and acting \_\_\_\_\_ of PULMONX CORPORATION, a Delaware corporation with offices located at 700 Chesapeake Drive, Redwood City, CA 94063 (“**Borrower**”), does hereby certify to **BOSTON SCIENTIFIC CORPORATION** (the “**Lender**”) in connection with that certain Second Lien Loan and Security Agreement dated as of May 15, 2017, by and between Borrower and the Lender (the “**Loan Agreement**”; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof; *provided, that* those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.
2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Term Loan to be made on or about the date hereof have been satisfied or waived by the Lender.
5. No Material Adverse Change has occurred.
6. The undersigned is a Responsible Officer.
7. The amount of the Term Loan requested by Borrower is \$\_\_\_\_\_.
8. The Term Loan shall be transferred as follows:

Account Name:	PULMONX CORPORATION
Bank Name:	[_____]
Bank Address:	[_____]
Account Number:	[_____]
ABA Number:	[_____]

***[Balance of Page Intentionally Left Blank]***

Dated as of the date first set forth above.

**BORROWER:**

PULMONX CORPORATION

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**EXHIBIT C**

**Form of Secured Promissory Note**

**[see attached]**



**THIS NOTE AND THE SECURITIES ISSUABLE UPON CONVERSION OF THIS NOTE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH SALE OR DISTRIBUTION MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO PULMONX CORPORATION (“BORROWER”) THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.**

**THIS NOTE AND THE RIGHTS AND OBLIGATIONS EVIDENCED HEREBY ARE SUBORDINATE IN THE MANNER AND TO THE EXTENT SET FORTH IN THAT CERTAIN SUBORDINATION AGREEMENT, DATED AS OF MAY 15, 2017 (AS AMENDED, THE “SUBORDINATION AGREEMENT”), AMONG OXFORD FINANCE LLC (“OXFORD”), BORROWER, AND BOSTON SCIENTIFIC CORPORATION (THE “LENDER”), TO (A) THE OBLIGATIONS OWED BY BORROWER AND OTHER OBLIGORS PURSUANT TO THAT CERTAIN LOAN AND SECURITY AGREEMENT, DATED AS OF AUGUST 28, 2014, AMONG BORROWER, OXFORD, AS A LENDER AND THE COLLATERAL AGENT THEREUNDER, AND THE OTHER LENDERS PARTY THERETO FROM TIME TO TIME, AS SUCH LOAN AND SECURITY AGREEMENT HAS BEEN AND HEREAFTER MAY BE AMENDED, RESTATED SUPPLEMENTED OR OTHERWISE MODIFIED FROM TIME TO TIME IN ACCORDANCE WITH THE TERMS OF THE SUBORDINATION AGREEMENT (THE “OXFORD LOAN AGREEMENT”), AND (B) OBLIGATIONS REFINANCING THE OBLIGATIONS UNDER THE OXFORD LOAN AGREEMENT AS CONTEMPLATED BY THE SUBORDINATION AGREEMENT.**

**THIS NOTE MAY BE ISSUED WITH ORIGINAL ISSUE DISCOUNT (“OID”) FOR U.S. FEDERAL INCOME TAX PURPOSES. THE ISSUE PRICE, AMOUNT OF OID, ISSUE DATE AND YIELD TO MATURITY WITH RESPECT TO THIS NOTE MAY BE OBTAINED BY WRITING TO BORROWER AT THE FOLLOWING ADDRESS: [\_\_\_\_\_] ATTENTION: [\_\_\_\_\_] FAX NUMBER: [\_\_\_\_\_]**

**SECURED CONVERTIBLE PROMISSORY NOTE**

\$ \_\_\_\_\_ Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, PULMONX CORPORATION, a Delaware corporation with offices located at 700 Chesapeake Drive, Redwood City, CA 94063 (“**Borrower**”) HEREBY PROMISES TO PAY to the order of BOSTON SCIENTIFIC CORPORATION (“**Lender**”) the principal amount of [\_\_\_\_\_] DOLLARS (\$\_\_\_\_\_) or such lesser amount as shall equal the outstanding principal balance of the Term Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term Loan, at the rates and in accordance with the terms of the Loan and Security Agreement, dated as of May 15, 2017, by

and between Borrower and Lender (as amended, restated, supplemented or otherwise modified from time to time, the “**Loan Agreement**”).

1. **Definitions.** Capitalized terms used in this Secured Convertible Promissory Note (this “**Note**”) and not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

2. **Payment.** If not sooner paid in accordance with the terms of the Loan Agreement, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Principal, interest and all other amounts due with respect to the Term Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Note. The Loan Agreement, among other things, contains provisions for acceleration of the maturity hereof upon the happening of certain stated events. This Note may not be prepaid, in whole or in part, except as set forth in the Loan Agreement.

3. **Conversion.** This Note is convertible into Conversion Stock pursuant to the terms of the Loan Agreement.

4. **Secured Obligation.** This Note and the obligation of Borrower to repay the unpaid principal amount of the Term Loan, interest on the Term Loan and all other amounts due Lender under the Loan Agreement is secured pursuant to the terms of the Loan Agreement.

5. **Miscellaneous.**

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable and documented attorneys’ fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower’s obligations hereunder not performed when due in accordance with the Loan Agreement.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

***[Balance of Page Intentionally Left Blank]***

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

**BORROWER:**

PULMONX CORPORATION

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_