

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

**FORM 10-K**

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

For the fiscal year ended December 31, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
Commission File Number 001-39562

**PULMONX CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

700 Chesapeake Drive  
Redwood City, California 94063  
1-650-364-0400

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller

reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

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

As of February 23, 2022, there were 37,018,943 shares of the Registrant's Common Stock, par value \$0.001 per share, outstanding.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2021, was approximately \$1.2 billion. Solely for the purposes of this disclosure, shares of common stock held by executive officers and directors have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not a conclusive determination for other purposes.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement relating to its 2022 annual meeting of stockholders (the "2022 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2022 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management’s good faith beliefs as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “anticipate,” “project,” “target,” “design,” “estimate,” “predict,” “potential,” “plan” or the negative of these terms, or similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth in Part I, Item 1A “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Forward-looking statements 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 severe emphysema, a form of chronic obstructive pulmonary disease (“COPD”);
  - our expectations regarding the impact of the COVID-19 pandemic on our business;
  - 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 and technologies in our industry;
  - our ability to develop and maintain our corporate infrastructure, including an effective system of internal controls and the remediation of any material weaknesses thereunder;
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- our financial performance and capital requirements;
- 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; and
- we have identified a material weakness in our internal controls over financial reporting, and if we are unable to remediate such material weakness and maintain an effective system of internal controls in the future, we may fail to timely and accurately report our financial results, experience a loss of investor confidence in the accuracy and completeness of our consolidated financial statements, incur material misstatements in our consolidated financial statements, and the market price of our common stock may be adversely affected.

All forward-looking statements are based on information available to us on the date of this Annual Report on Form 10-K and we will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K, except as required by law. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, and you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within Part I, Item 1A, “Risk Factors” of this Annual Report on Form 10-K.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

*All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders. Unless the context requires otherwise, references in this Annual Report on Form 10-K to “Pulmonx” the “Company,” “we,” “us,” and “our” refer to Pulmonx Corporation.*

### **Risk Factors Summary**

*Below is a summary of the principal factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under “Special Note Regarding Forward-Looking Statement” and Part I, Item 1A, “Risk Factors” in this Annual Report on Form 10-K. The below summary is qualified in its entirety by those more complete discussions of such risks and uncertainties. You should consider carefully the risks and uncertainties described under Part I, Item 1A, “Risk Factors” in this Annual Report on Form 10-K as part of your evaluation of an investment in our common stock:*

- 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 Endobronchial Valve (“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;
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- 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;
  - The COVID-19 pandemic has had a material adverse impact on our business, financial condition and results of operations, and may continue to impact us in the future;
  - 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 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 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.
-

## PART I

### ITEM 1. BUSINESS

#### 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 100,000 valves used to treat more than 25,000 patients. 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.



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 25,000 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. Our sales territory managers are focused on promoting awareness and increasing adoption of our solution primarily among the pulmonologists performing interventional pulmonary procedures across approximately 500 high volume hospitals in the United States. 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 APC and MS-DRG payment groupings. Current reimbursement in the United States is believed to cover the hospital costs of the procedure and related inpatient care. Commercial payors such as Aetna, Humana, Health Care Service Corporation, and Highmark 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 generated revenue of \$48.4 million, with a gross margin of 73.6% and a net loss of \$48.7 million, for the year ended December 31, 2021 compared to revenue of \$32.7 million, with a gross margin of 64.8% and a net loss of \$32.2 million, for the year ended December 31, 2020. As of December 31, 2021, we had an accumulated deficit of \$291.4 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 Market Opportunity**

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

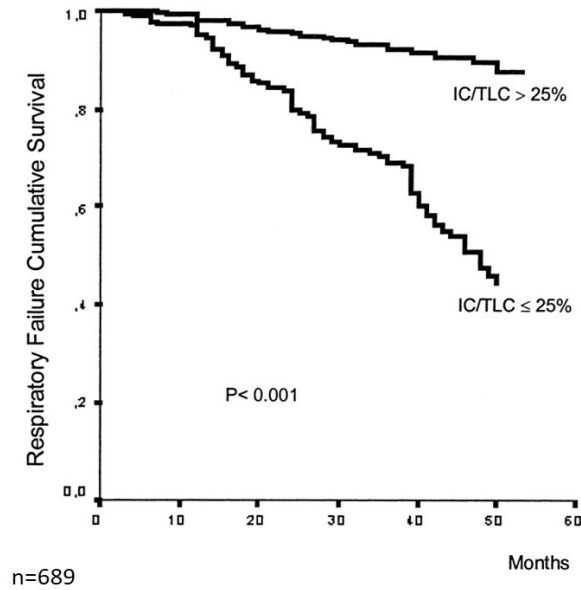
COPD refers to a group of lung diseases characterized by obstruction of airflow that interferes with normal breathing. In 2015, it affected approximately 175 million patients and was responsible for 3.2 million deaths globally. We estimate that there are approximately 8.5 million severe COPD patients in developed markets globally as of 2019. In the United States, COPD is the third leading cause of death and affected approximately 16 million Americans as of 2013.

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. Of the approximately 8.5 million global 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. We estimate this represents a global market opportunity of approximately \$12 billion.

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. We estimate this represents a U.S. market opportunity of approximately \$5 billion.

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 inflate more fully. 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.

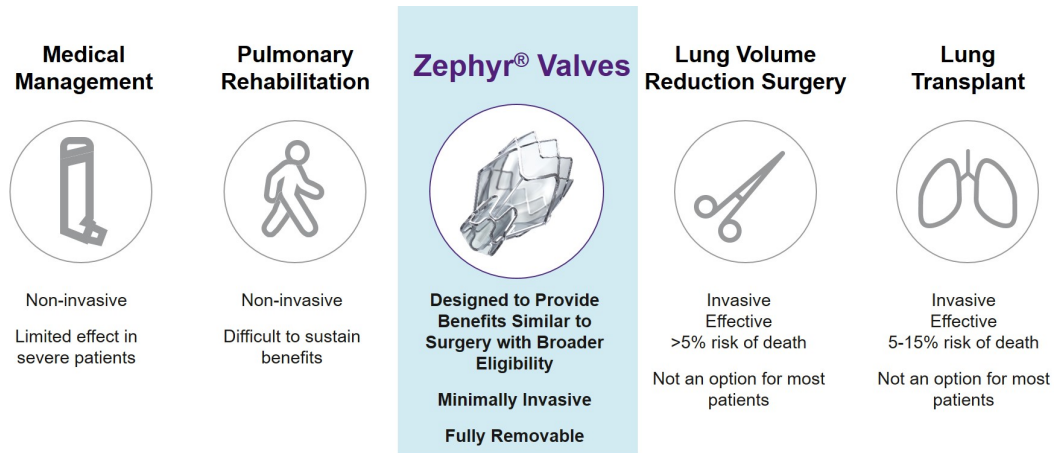
Lung transplantation involves surgically removing one or both lungs and replacing them with donor lungs. This procedure is highly time and resource intensive due to the complexity of the surgery. Even with a successful procedure and consistent use of anti-rejection medications, lung transplantation patients 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 more than 25,000 patients treated globally with Zephyr Valves;
- **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).



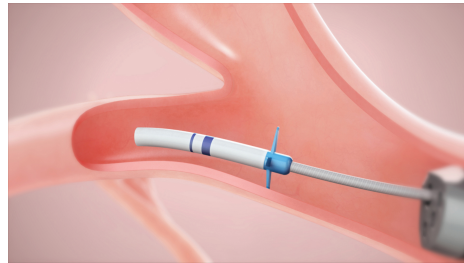
**4.0-LP EBV**

**4.0 EBV**

**5.5-LP EBV**

**5.5 EBV**

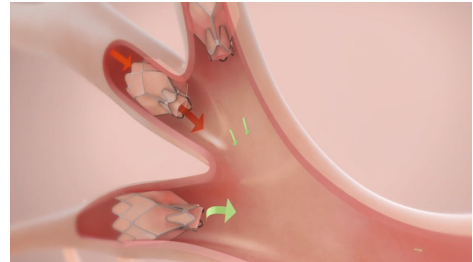
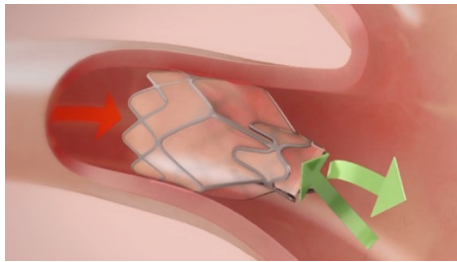
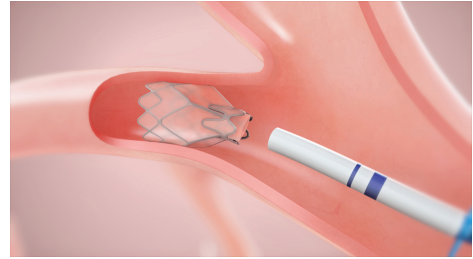
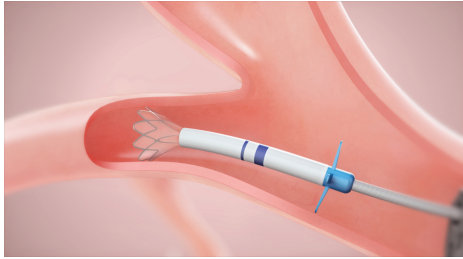
Physicians select the optimal valve size for each airway to be treated using an EDC that includes sizing wings and depth markers, which allows the physician to perform quick and accurate sizing.



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.

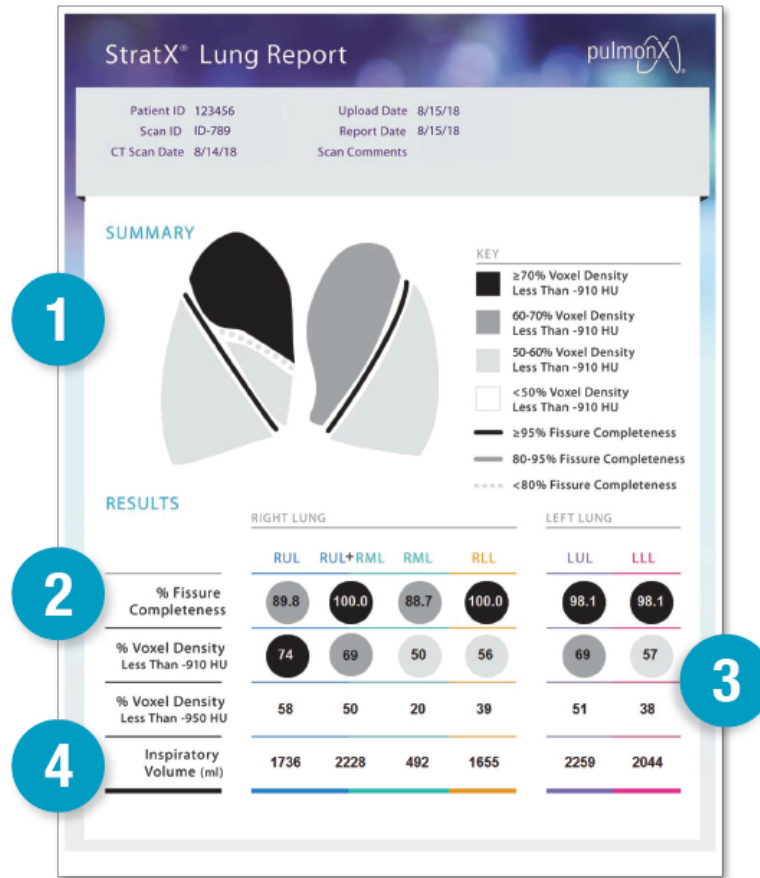
## **StratX Platform**

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.

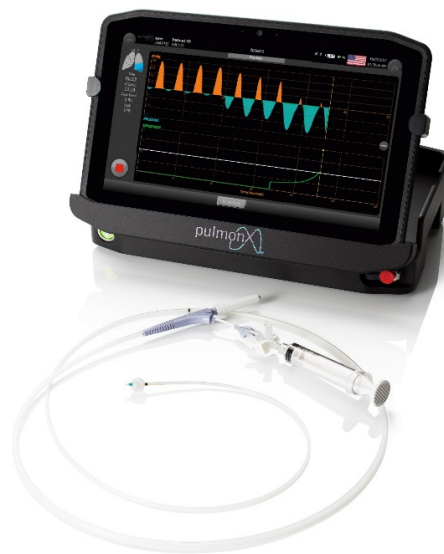
3. **Emphysema Destruction Scoring:** Lobar destruction values of greater than 50% at -910 Hounsfield Units (a measure of tissue density) have been commonly used as an inclusion criterion for various clinical trials of Zephyr Valve treatment. The StratX Lung Report also includes lobar destruction values 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.

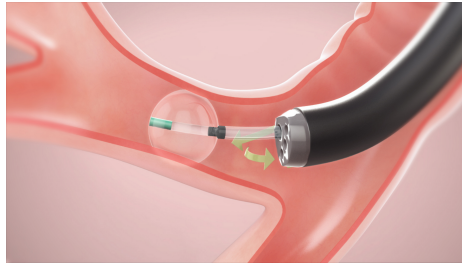
We continue to gather scan data and refine our algorithms in the StratX Platform. We believe that our high volume of reports and data are a source of durable competitive advantage.

### 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.

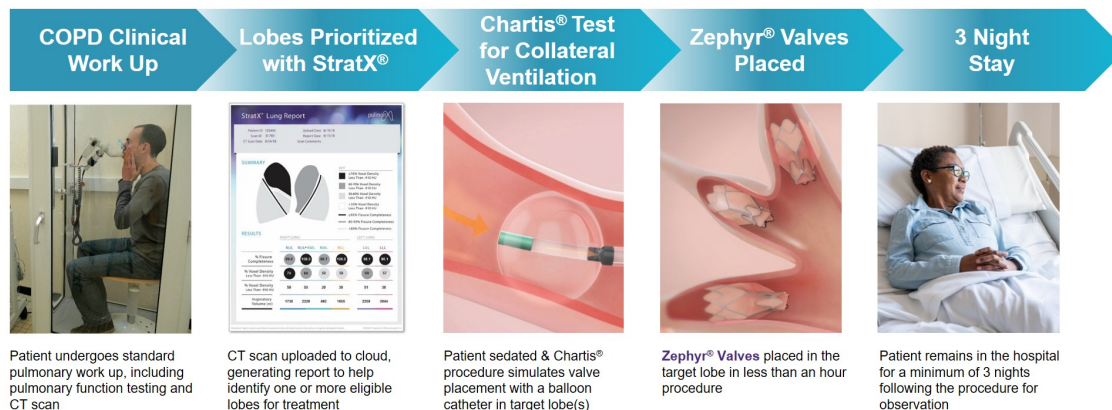
The Chartis System offers a physiologic technique for measuring collateral ventilation and complements non-invasive estimates of fissure completeness. Other methods, such as using fissure analysis as a proxy measurement of collateral ventilation allows detection of an incomplete boundary between the lobes but does not measure how much air is flowing across this gap. Without assessment by the Chartis System, physicians may treat a lobe that has collateral ventilation, which will likely not respond to valve treatment, or unnecessarily rule out a patient who could have potentially benefitted from 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.



### 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 (“UK”) 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 have established a similar registry in France.

### Summary of Key Clinical Results

As seen in the 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 (SGRO) † 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 ( $p < 0.001$ ).

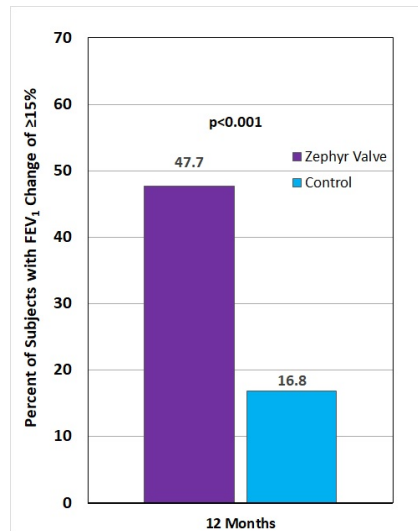


Figure shows the primary endpoint of FEV<sub>1</sub> Responders (FEV<sub>1</sub> improvement of  $\geq 15\%$ ) at 12 months

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,  $p = 0.004$ ).

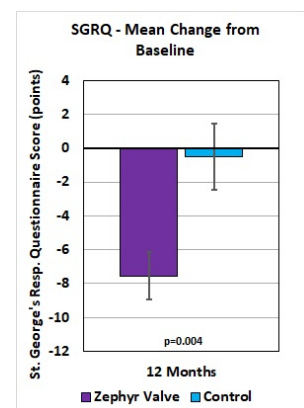
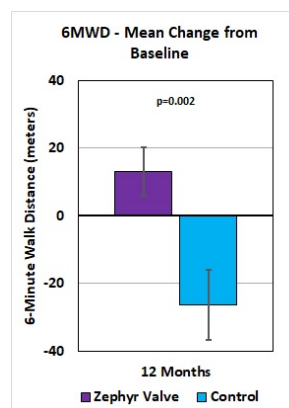
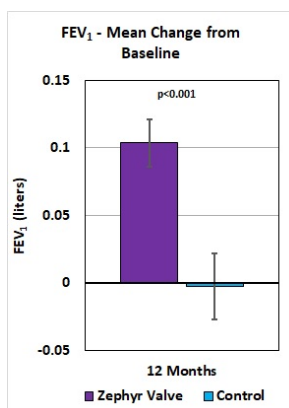


Figure above presents secondary endpoints as mean changes  $\pm$  standard error of the mean (SEM) from baseline to 12 months for the Zephyr Valve and Control Groups

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.

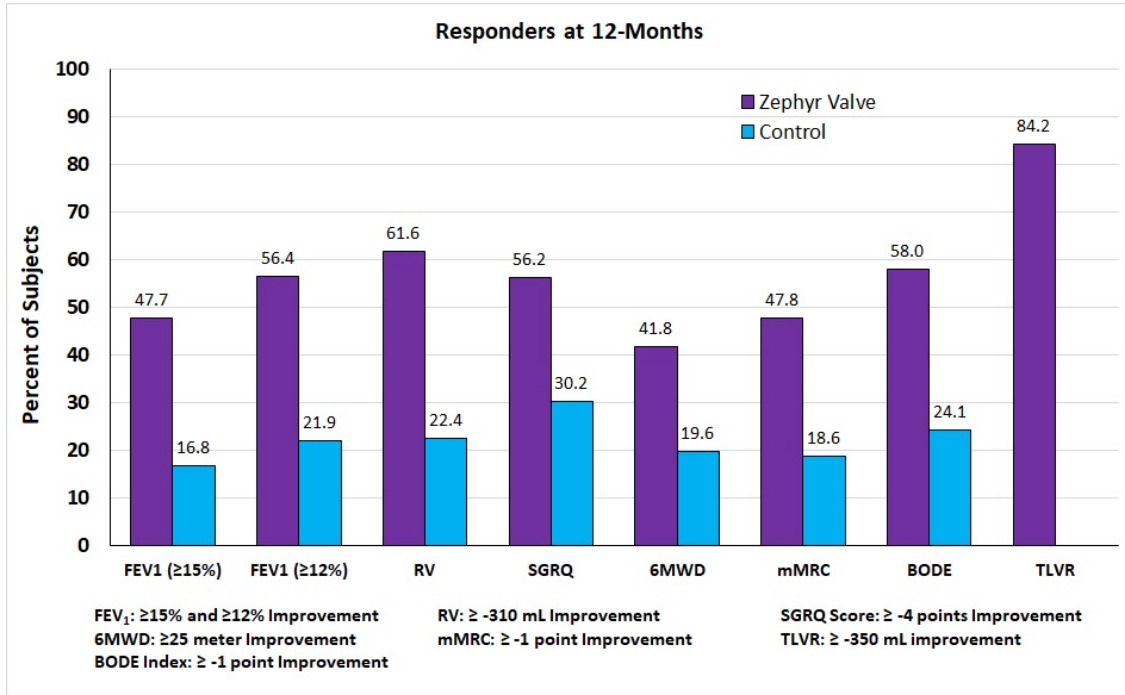


Figure above shows Responder rates based on individual MCID for various endpoints at 12 months

## Safety

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	Δ Zephyr Valve - Control	Zephyr Valve N=128	Control N=62	Δ 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%

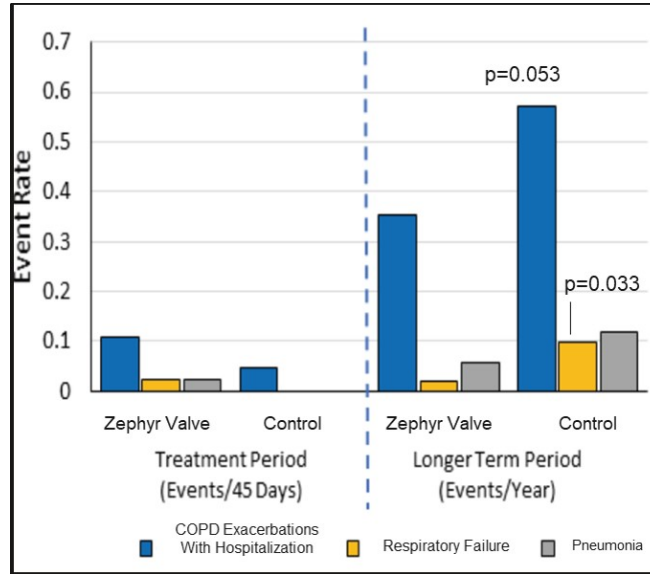
There were a higher number of serious adverse events in the Zephyr Valve Group compared to the Control Group during the Treatment Period. The most common serious adverse events in the Zephyr Valve Group versus the Control Group during the Treatment Period were pneumothorax and COPD exacerbations.

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 Part I, Item 1A, “Risk Factors—Risks Related to Our Business and Strategy—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.”

*Additional Post Hoc Analysis of LIBERATE Data*

In July 2020, Dransfield et al. published a post hoc analysis of patient reported outcomes (PRO) from the LIBERATE trial which found that patients with severe emphysema and hyperinflation who achieve lung volume reduction following treatment with Zephyr Valves experience moderate to large improvements in multidimensional scores for breathlessness, activity, and psychosocial parameters that may permit re-engagement in activities of daily living out to at least 12 months. Patients treated with the Zephyr Valves also reported experiencing significantly more days when their symptoms were “better” and fewer days that were “worse” over 12 months compared to the control group. The authors concluded that interruption of the downward spiral of symptom-induced inactivity, muscle deconditioning, and ensuing weakness allows patients to experience improved activity, feeling of well-being, more confidence, and a better quality of life.

*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.

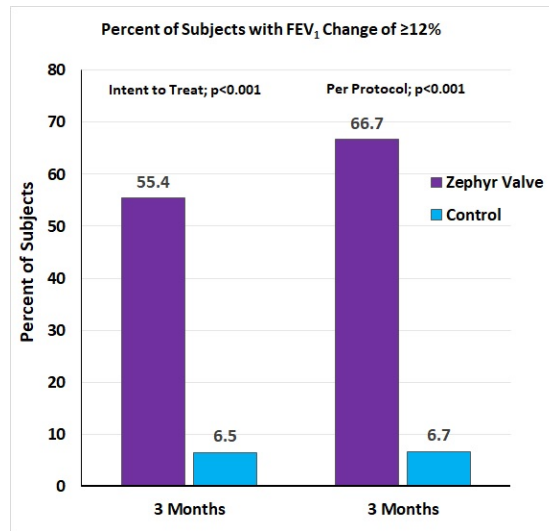
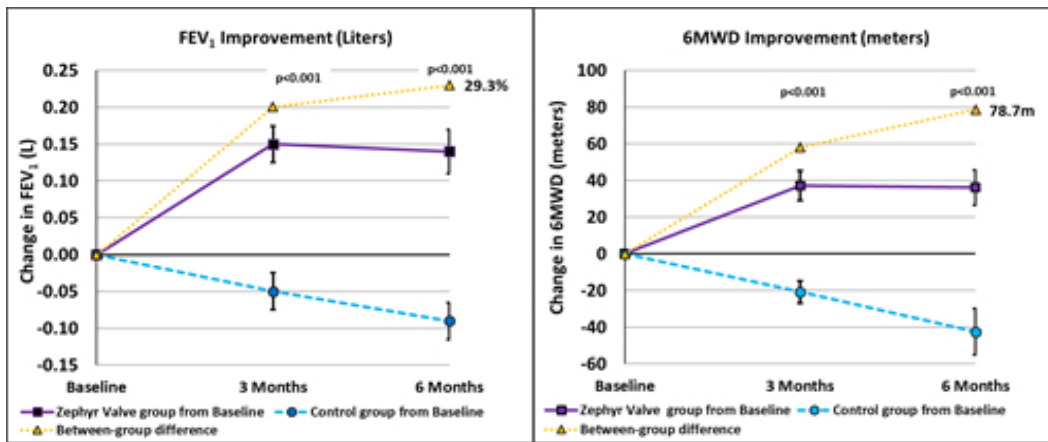
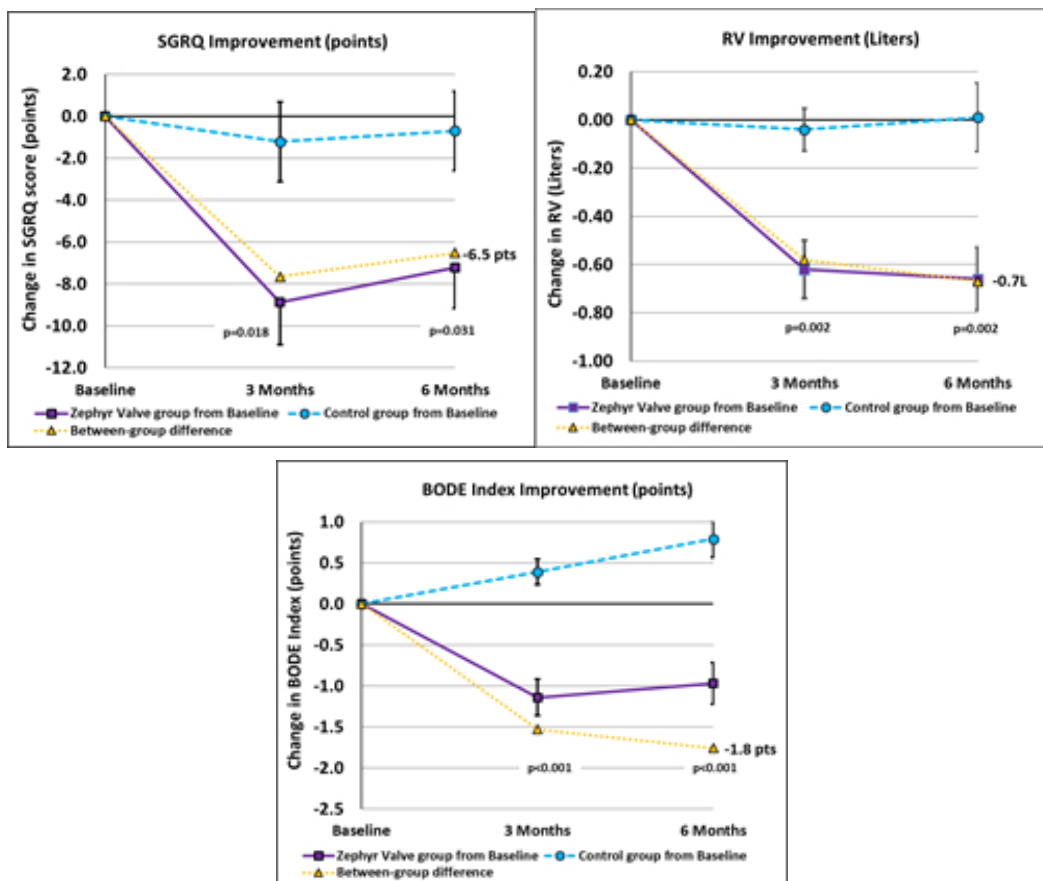


Figure above shows the responder rate (primary endpoint) for the Intention-to-Treat and Per Protocol Populations at three months

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 FEV1, 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—Risks Related to Our Business and Strategy—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).

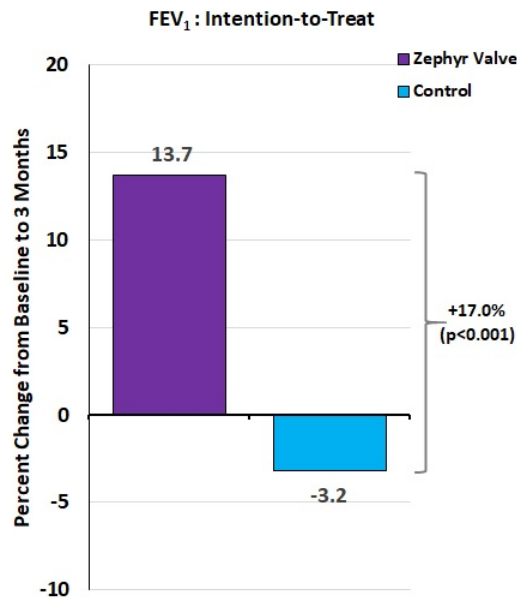


Figure above shows the percent change of FEV<sub>1</sub> from baseline (primary endpoint) for the ITT groups at three months

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.

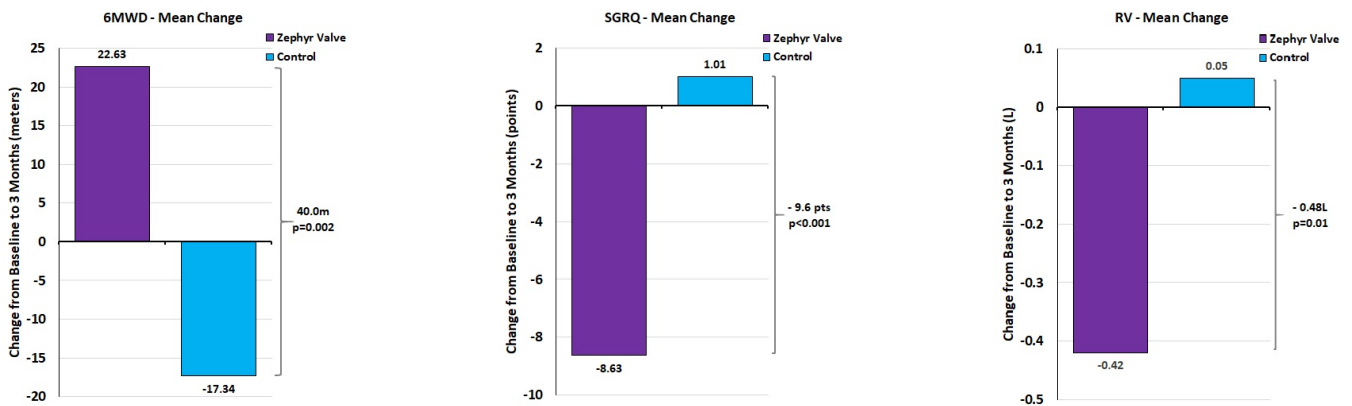


Figure above presents secondary endpoints as mean changes ± SEM from baseline to six months for the Zephyr Valve and Control Groups

### 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 Part I, Item 1A, “Risk Factors—Risks Related to Our Business and Strategy—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 homogeneous 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.

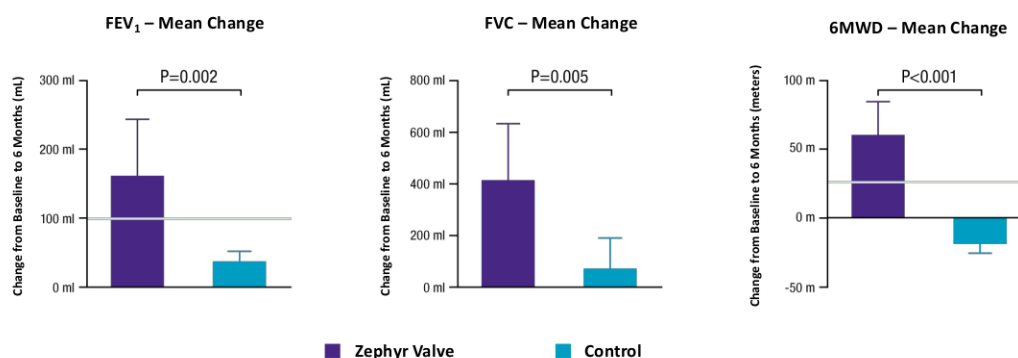


Figure above presents the co-primary endpoints as mean changes with 95% confidence intervals from baseline to six months for the Zephyr Valve and Control Groups

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

	Zephyr Valve Group N=34	Control Group N=34	Difference Between Groups (Zephyr Valve - Control)
FEV <sub>1</sub> (%)	20.9	3.1	17.8
FVC (%)	18.3	4	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

	Homogeneous Emphysema N=29	Heterogeneous Emphysema N=22
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 Part I, Item 1A, “Risk Factors—Risks Related to Our Business and Strategy—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.”

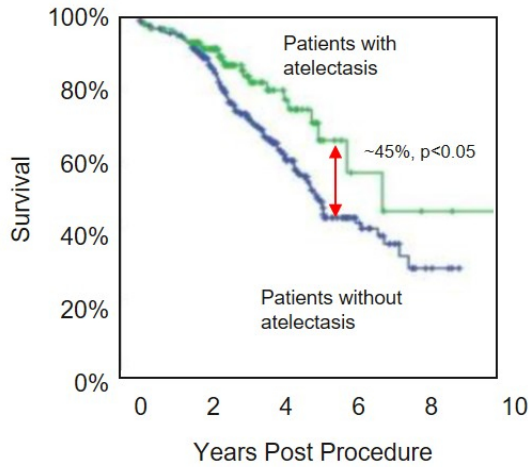
#### *Other Clinical Trials*

The VENT study was a multicenter 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.

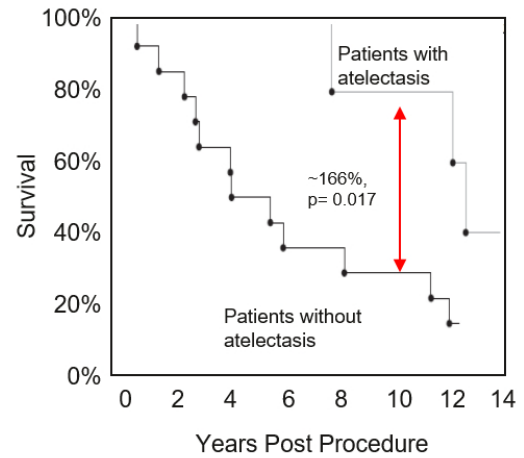
We are not aware of any prospective data regarding survival rates of patients who have undergone endobronchial valve treatment. There are two survival studies, however, that retrospectively evaluate patients treated with endobronchial valves. These studies compared survival rates between patients with significant volume reduction in the treated lobe (also called atelectasis) against those who did not have atelectasis. In one study, the patient population consisted of 449 patients with either heterogeneous or homogeneous emphysema five years following treatment with Zephyr Valves or other endobronchial valves. The majority of patients in this study were treated with Zephyr Valves. The results of this study suggested that patients with atelectasis were approximately 45% more likely to survive than patients without. Another study of 19 patients with only heterogeneous emphysema ten years following treatment with Zephyr Valves suggested that patients with atelectasis were approximately 166% more likely to survive than patients without atelectasis. We believe these studies are relevant because treatment with Zephyr Valves is intended to cause atelectasis in poorly functioning, hyperinflated lobes of the lung. In addition, the results of these studies add to the body of evidence showing the benefits of atelectasis in patients with severe

emphysema and hyperinflation, including the potential for increased survival rates when compared to valve treatment without atelectasis.



Gompelmann et. al (2019): Survival after Endoscopic Valve Therapy in Patients with Severe Emphysema. *Respiration*; 97; 145-152.

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Garner et al (2016): Survival after Endobronchial Valve Placement for Emphysema: A 10-Year Follow-up Study. *Amer J Respir Crit Care Med*.194 (4): 519-521.

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### 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 seek to recruit sales territory managers with strong sales backgrounds, with direct experience developing markets with new technologies and an understanding of medical device reimbursement. 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, various medical societies, and prospective patients 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 supporting 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 information and news.

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.

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 access 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 APC and MS-DRG 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 items and services 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 generally 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 patient demographic information and ICD-10-CM diagnosis and ICD-10 PCS codes that describe the patient's diagnoses and procedures performed during the hospital stay.

#### ***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 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 ICD-10 PCS procedure codes that best describe our procedure map to the MS-DRG classifications for Major Chest Procedures, depending on comorbidities and complications. MS-DRG classifications 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, while physician charges associated with performing medical procedures are reimbursed to physicians through a different payment system based on the codes they submit. 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 typically discharged the same day and the procedure therefore billed as an outpatient procedure. The national average payment for this procedure is sufficient to cover costs of the procedure. 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 processed by Medicare Administrative Contractors ("MACs"), which assess coverage under Medicare's reasonable and necessary standard. We estimate that roughly 75% of the potential Zephyr Valve patient population are Medicare/Medicaid beneficiaries of which approximately 30% have managed Medicare/Medicaid and the remaining 45% have traditional fee-for-service 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.

Commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, and BCBS Michigan have all issued positive coverage policies for the Zephyr Valve, and United Healthcare no longer considers the procedure unproven or experimental. 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 safety 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 for payers that require it. 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 streamlined 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 national health care systems or private health insurance plans, or combinations thereof. We have established market access in countries across Europe and Asia Pacific, including Australia, Austria, Belgium, France, Germany, the Netherlands, United Kingdom, Scotland, Switzerland and South Korea, and other countries. The procedure is now included as a treatment option in national and international COPD management and treatment guidelines across Europe and Asia Pacific.

### **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 expanding the Zephyr Valve indication to include the management of persistent air leaks.

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 polymerizing sealant that can be delivered via a bronchoscope to a targeted region of the lung to reduce volume in the treated area. We believe that AeriSeal 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 have funded an independent feasibility study using AeriSeal and sponsored another study to expand the number of patients that can be treated with Zephyr Valves. In December 2020, AeriSeal received designation as a Breakthrough Device by the FDA. The breakthrough designation will provide prioritized and potentially accelerated review by the FDA. We intend to submit an IDE to the FDA for commencing a clinical trial with the AeriSeal system. If successfully developed and approved, AeriSeal could further expand the addressable market of our solution.

For the years ended December 31, 2021 and December 31, 2020, we incurred research and development expenses, including our clinical trials, of \$13.1 million and \$7.5 million, respectively.

### **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 homogeneous 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 competitors have several competitive advantages, including more established operating histories, established relationships with pulmonologists who commonly treat patients with emphysema, significantly greater name recognition, widespread distribution channels, 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, 2021, we had 38 patent families in force worldwide. As of December 31, 2021, we had rights to 58 issued United States patents, 18 pending United States patent applications, 125 issued foreign patents and 15 pending foreign patent applications. Our most material foreign patents issued and patent applications pending are in the European Union (“EU”), 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 2022 and 2041. 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 Part I, Item 1A, “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, 2021, we had nine 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 operations, including manufacturing and quality control. We lease additional facilities in Redwood City, California of approximately 8,000 square feet and 17,000 square feet of space under lease agreements that terminates on May 31, 2024 and September 30, 2024, respectively. These facilities support finished goods storage and distribution. We have manufactured all our products at this facility for over 10 years and to date we have manufactured over 80,000 Zephyr Valves. There is a mutual early termination option starting November 30, 2021 on the 8,000 square feet of space.

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 headquarters in Redwood City. 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 third-party logistics provider in Memphis, Tennessee and our facilities in Redwood City 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 facilities 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 Medical Device Directive ("MDD") or Medical Device Regulation ("MDR") 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. BSI will audit our facility to the MDR during 2022.

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 (“FDA”)***

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 (“IDE”)***

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, 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”) and, starting on May 26, 2021, the Medical Device Regulation (Regulation (EU) 2017/745) (“MDR”). The MDR sets out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDR 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 MDR. 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 under the MDD. We will obtain a CE mark under the MDR prior to the expiration of the existing CE certificate.

#### *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 as well as their covered subcontractors, 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.

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.

#### *Privacy and Information Security Laws*

In the ordinary course of our business, we may process personal data, including health data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the Federal Trade Commission Act, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003, the California Consumer Privacy Act of 2018 ("CCPA"), the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), and the EU GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"). In addition, states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act and Colorado passed the Colorado Privacy Act.

The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing and that increase our compliance obligations and exposure for any non-compliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collecting, using and disclosing personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches that may include an award of statutory damages. In addition, it is anticipated that the California Privacy Rights Act of 2020 ("CPRA"), effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on personal data retention, expand the types of data breaches subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. US federal and state consumer protection laws may require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

European data protection laws (including the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. For example, the EU GDPR applies to any company established in the European Economic Area ("EEA") and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing only to what is necessary for specified, explicit and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authorities and affected individuals; and mandating the appointment of representatives in the United Kingdom and/or the European Union in certain circumstances.

See also Part I, Item 1A, “Risk Factors—Risks Related to Government Regulation and Our Industry” for additional information about the laws and regulations to which we are or may become subject and the risks to our business associated with such laws and regulations.

### **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. If our operations are found to be in violation of any of the federal, state and foreign laws described below 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, additional oversight and reporting obligations, 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.

#### ***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. 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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and applicable manufacturers and group purchasing organizations, as well as information regarding ownership and investment interests held by physicians and their immediate family members. These reporting obligations include payments and other transfers of value made in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives. 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 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 Bribery Act, 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 (“CMS”)***

Medicare is a federal program administered by CMS through Medicare Administrative Contractors. 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 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. There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress considered legislation to 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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. On January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future, including congressional legislation to modify or replace the Affordable Care Act or elements of the Affordable Care Act. It is unclear how such challenges and the healthcare reform measures of the Biden administration 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, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare

payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

## **Human Capital Management**

### *Employees*

As of December 31, 2021, we had a total of 253 employees, with 198 employees in the U.S., 39 in Europe, and 16 in Asia Pacific. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We believe that we have good relations with our employees.

### *Code of Business Conduct and Business Ethics*

Pulmonx is dedicated to conducting its business consistent with the highest standard of business ethics. Each employee receives and agrees to follow the Pulmonx Code of Business Conduct and Ethics. Employees are encouraged to discuss any related concerns with management or report concerns anonymously through an Ethics Hotline.

### *Culture of Diversity, Equity, and Inclusion*

At Pulmonx, we value diverse perspectives and experiences. We continue to create an inclusive culture where differences drive innovation. In 2021, our task force identified opportunities to increase awareness as well as initiatives to identify, attract and retain underrepresented diverse talent.

### *Talent Management & Development*

We believe that our employees are the foundation of our business and we are committed to the development and retention of our workforce. Our goal at Pulmonx is to become a “Talent Destination.”

### *Compensation Philosophy*

To ensure we are able to attract, retain and develop high performing teams, we engage external compensation advisors to guide our efforts in developing cash and equity rewards programs that are competitive with our peer companies.

### *Total rewards*

We offer competitive health and welfare programs to support our employees and their families’ physical, mental, and financial well-being. Our program offerings include the following:

- Medical, dental and vision insurance
- Retirement plan

- Flexible Spending Accounts for medical expenses, childcare, parking and transit
- Life insurance
- Short & long-term disability
- Paid time off
- Employee assistance program

In an effort to further align the interests of our employees with our shareholders, employees in most countries in which we operate have the opportunity to have an ownership interest in our company. We have an equity-based incentive plan that provides for the grant of stock options and awards to eligible employees. Additionally, we implemented an Employee Stock Purchase Plan that enables eligible employees to purchase our common stock at a discount through payroll contributions.

#### *COVID-19 Health and Safety*

The health and safety of our employees is a key focus at our Company. In response to the COVID-19 pandemic, the Company established safety protocols, facility enhancements, and work from home strategies to protect our employees. Some of our employees continue to work remotely. Employees that work on site are provided with personal protective equipment and are required to adhere to protocols for wearing masks at all times, social distancing, and reporting and documenting exposures, all following guidelines issued by the Centers for Disease Control or mandated by local regulations.

#### **Available Information**

Our website address is [www.pulmonx.com](http://www.pulmonx.com). Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K. We file electronically with the U.S. Securities and Exchange Commission, or SEC, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at [www.pulmonx.com](http://www.pulmonx.com), free of charge, copies of these reports and other information as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. All SEC filings are also available at the SEC's website at [www.sec.gov](http://www.sec.gov)

## ITEM 1A. RISK FACTORS

*Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Annual Report on Form 10-K, including our audited consolidated financial statements and the related notes and Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.*

### **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 years ended December 31, 2021 and 2020, we had net losses of \$48.7 million and \$32.2 million, respectively, and we expect to continue to incur additional losses. As of December 31, 2021, we had an accumulated deficit of \$291.4 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. 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 impact of the COVID-19 pandemic on our business, financial condition and results of operations;
- 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 and delivery catheters accounted for most of our revenue for the years ended December 31, 2021 and 2020 and we expect that sales of Zephyr Valves and delivery catheters will continue to account for most 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, Anthem Blue Cross Blue Shield, Blue Cross Blue Shield of Michigan, Humana, Health Care Service Corporation, and Highmark, other commercial payors, including other plans in 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 increase 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;
- a decrease or delay in the number of procedures performed using our solution as a result of the COVID-19 pandemic;
- 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. Patients may not adopt our solution if they are reluctant to undergo a minimally invasive procedure, if they are worried about potential adverse effects of our solution, such as infection, discomfort or weakness, or if 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 (“EU”), 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.

***The COVID-19 pandemic has had a material adverse impact on our business, financial condition and results of operations, and may continue to impact us in the future.***

The COVID-19 pandemic has had a material adverse impact on our business, financial condition and results of operations by decreasing and delaying procedures performed using our products, and the pandemic may continue to adversely impact our business, financial condition and results of operations in the future. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our products have been substantially impacted as healthcare organizations across the globe have prioritized the treatment of patients with COVID-19 or have altered their operations to respond to the pandemic. For example, in the U.S., governmental authorities recommended, and, in certain cases, required, that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. As a result, the COVID-19 pandemic has adversely impacted the number of procedures using the Zephyr Valve as hospitals have had to focus on COVID-19 and as patients generally sought to postpone healthcare visits and treatments. The COVID-19 pandemic and related governmental and societal responses to mitigate its impact have caused, and may in the future cause, decreased demand for procedures using our products, a global slowdown of economic activity, volatility and disruption of financial markets, supply chain disruptions, and changes in behavior of healthcare organizations.

Despite signs of recovery in some regions of our U.S. markets, we may continue to see regional variations in procedure volumes from a resurgence of the COVID-19 pandemic and its variants. In international markets, our business faced continued pressure in the fourth quarter of 2021 as a result of the COVID surge that led to lockdowns across a number of markets in Europe. During the fourth quarter of 2021, sales increased in regions of the U.S. less affected by COVID-19, which were partially offset by decreased sales in US regions significantly impacted by the

Delta and Omicron variants of COVID-19. We cannot be certain that any recovery will be sustained, or that a further resurgence of COVID-19 will not occur, including, for example, in the U.S. and Europe where there have been increasing cases from COVID-19 variants. Many of the measures adopted in response to, and challenges resulting from, COVID-19 may continue for the duration of the pandemic, which is uncertain, and could significantly reduce our revenue and adversely impact our business, financial condition and results of operations for the duration of the pandemic. As a result, we cannot assure you that our recent volume of Zephyr Valves sold are indicative of future results or that we will not experience additional adverse or materially adverse impacts associated with the COVID-19 pandemic. Further, there may be limited provider capacity due to labor shortages, or for other reasons, which could limit the ability of patients to receive treatment with Zephyr Valves. This limited provider and hospital capacity could have a material adverse effect on our business, financial condition and results of operations as the pandemic subsides and following the end of the pandemic.

The severity, magnitude and duration of the COVID-19 pandemic, the public health responses and its economic consequences, as well as the efficacy, availability and distribution of vaccines, remain uncertain, rapidly changing and difficult to predict. The pandemic's impact on our financial condition and results of operations performance, as well as its impact on our ability to successfully execute our business strategies and initiatives, also remains uncertain and difficult to predict. To the extent the pandemic continues to disrupt economic activity globally, it could adversely affect our ability to access capital, which could in the future negatively affect our liquidity. In addition, depressed economic activity resulting from the COVID-19 pandemic could have a material adverse effect on our long-term business as hospitals curtail and reduce capital and overall spending. For example, economic market disruptions may result in significant job losses and reductions in disposable income. If patients are unable to obtain or maintain health insurance policies, it may significantly impact their ability to pay for the procedures utilizing our products, further negatively impacting our business, financial condition and results of operations.

We continue to monitor the rapidly evolving situation and guidance from domestic and international authorities, including federal, state and local public health authorities, and there may be developments outside our control requiring us to adjust our business strategies and operating plan. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

***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 (which received medical management alone). 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 substantially all of our revenue from the sale of our products to hospitals and distributors 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, 2021, commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, and BCBS Michigan 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, including other 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 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, Austria, Belgium, France, Germany, the Netherlands, United Kingdom (the “UK”), Scotland, Switzerland and South Korea, 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, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage is established on one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 will 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 alternatives. 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. We also store finished goods at secondary facilities in Redwood City, California, Memphis, Tennessee and the Netherlands. If these facilities suffer 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;
- disruptions in our production schedule and ability to manufacture and assemble products due to the COVID-19 pandemic;
- 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 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 future 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 beginning and end of the year 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 ongoing and global impact that the COVID-19 pandemic had and may continue to have on our business and the number of patients treated with Zephyr Valves, or any other pandemic, epidemic or outbreak of an infectious disease;
- 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 the 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. Our Swiss subsidiary is also currently party to a lawsuit with a former distributor outside the United States alleging that our Swiss subsidiary terminated the agreement without proper compensation. While we believe these claims are meritless and, if successful, we 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. 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.***

In February 2020, we executed a Loan and Security Agreement (the “CIBC Agreement”) with Canadian Imperial Bank of Commerce (“CIBC”), which provided us with the ability to borrow up to \$32.0 million in debt financing. As of December 31, 2021, we have borrowed \$17.0 million under the CIBC Agreement. See the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources; Plan of Operation—2020 Notes,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources; Plan of Operation—CIBC Loan” and the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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 CIBC 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;
- enter into transactions with our affiliates; and
- under certain circumstances, settle pending or threatened litigation for greater amounts than are disclosed to CIBC in writing from time to time.

There can be no guarantee that we will not breach these covenants. 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 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, 2021, we had \$191.0 million

in cash, cash equivalents and marketable securities, and an accumulated deficit of \$291.4 million. Based on our current planned operations, we expect our cash, cash equivalents and short-term marketable securities, together with available borrowings under the CIBC Agreement, 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 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 impact of the COVID-19 pandemic on our business;
- 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 in a single location at our headquarters in Redwood City, California. We store our finished goods inventory at our headquarters and secondary facilities in Redwood City, California, Memphis, Tennessee, and the Netherlands. Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The facilities 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.

Further, 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 48.4% and 50.5% of our revenue for the years ended December 31, 2021 and 2020, respectively. We currently focus our international sales and marketing efforts in Australia, Austria, Belgium, China, Denmark, France, Germany, Ireland, 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, including as a result of armed conflict, war or the threat of war, terrorist activity and other security concerns in general;
- global health epidemics or other contagious diseases, including the impact of the COVID-19 pandemic;
- 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.

For example, the COVID-19 pandemic significantly decreased and may continue to have an adverse impact on the sale of our products and the number of patients treated with our solution. The outbreak has also resulted in disruptions or restrictions on physicians, hospitals and other healthcare providers from treating patients that are eligible for our products due to the uncertain health effects of the coronavirus on the respiratory system and resources that are diverted to prioritize treatment and containment of the coronavirus outbreak. In addition, the COVID-19 pandemic has also resulted in business closures and disruptions that may continue to affect various suppliers of ancillary products used in the delivery of our product (e.g. gowns, face masks or gloves), including disruptions and restrictions on transportation of our products and could result in significant delays. In addition, a significant outbreak of coronavirus and other contagious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could affect demand for our products and impact our business, financial condition and results of operations.

If one or more of these risks are realized, it will negatively affect our business, financial condition and results of operations.

***If our information technology systems or data is or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, and a loss of customers or sales.***

In the ordinary course of our business, we and third parties upon which we rely may become exposed to, or collect and store sensitive data, including procedure-based information, 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 third parties, including technology partners and providers, may be vulnerable to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), ransomware attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fire, flood, and other similar threats. In addition to traditional computer “hackers” and threat actors, sophisticated nation-state, nation-state supported, and criminal threat actors now engage in attacks, including advanced persistent threat intrusions and ransomware attacks, the latter of which are becoming increasingly prevalent and severe. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our platform, systems and networks or the systems and networks of third parties that support us and our services. Additionally, the COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises.

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. For example, companies have recently experienced an increase in phishing and social engineering attacks from third parties. 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, 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 of cybersecurity incidents 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. Advances in computer capabilities, new technological discoveries or other developments may result in cyberattacks becoming more sophisticated and more difficult to detect. We and our third-party service providers may not have the resources or technical sophistication to anticipate or prevent all such cyberattacks. Moreover, techniques used to obtain unauthorized access to systems or other information technology infrastructure change frequently and may not be detected until after an incident has occurred. 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.

If we or our third-party service providers experience, or are perceived to have experienced, material security breaches, it may result in: government enforcement actions that could include investigations, fines, penalties, audits and inspections; additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal data; or orders to destroy or not use personal data. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements, could lead to adverse impacts. Further, individuals or other relevant stakeholders could sue us for our actual or perceived failure to comply with our security obligations, including, without limitation, in class action litigation. Security incidents could also result in indemnity obligations, negative publicity and financial loss. There can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our security obligations. Security incidents and vulnerabilities may cause some of our customers and users to stop using our services and our failure, or perceived failure, to meet expectations with regard to the security, integrity, availability and confidentiality of our systems and sensitive data could damage our reputation and affect our ability to retain customers, attract new customers and grow our business. Any of these results could harm our growth prospects, our business and our reputation. Moreover, security incidents can result in the diversion of funds, and interruptions, delays, or outages in our operations and services, including due to ransomware attacks. Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions to our operations and adversely impact the confidentiality, integrity and availability of sensitive, proprietary or confidential information, and prevent us from administering our business.

***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, including due to the impact of the COVID-19 pandemic, 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.

Further, in late February 2022, Russia initiated significant military action against Ukraine. In response, the U.S. and certain other countries imposed significant sanctions and trade actions against Russia, and the U.S. and certain other countries could impose further sanctions, trade restrictions and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof, as well as any counter measures or retaliatory actions by Russia in response, is likely to cause regional instability, geopolitical shifts and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. In particular, while it is difficult to anticipate the impact of any of the foregoing on the Company, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely 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 payors 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.

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.

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 European Economic Area (“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.

The Medical Devices Regulation became applicable in 2021. These modifications may have an effect on the way we conduct our business in the EEA.

***Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed, cleared or approved or commercialized in a timely manner, which could negatively impact our business.***

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

Disruptions at the FDA and other agencies may also slow the time necessary for new devices to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA has had to postpone inspections of certain foreign and domestic manufacturing facilities and products, and is conducting inspections on a risk-based basis. Other regulatory authorities have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***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, created under the Patient Protection and 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 physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding 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 as well as their covered subcontractors; HIPAA also created criminal liability for, among other things, 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, 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, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral;
- 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, amended 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 continued 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, additional oversight and reporting obligations, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm and disfigurement 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 Regulation, 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 MDR, 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 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 the BSI in the Netherlands, our European Notified Body. Most recently, BSI completed an ISO 13485 surveillance audit of our design, manufacturing and service operations in April 2020 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 MDR. 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.

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

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

***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 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. 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. However, the 2020 federal spending package permanently eliminated this medical device excise tax effective January 1, 2020.

There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, former President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress considered legislation to 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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. In addition, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future, including congressional legislation to modify or replace the Affordable Care Act or elements of the Affordable Care Act. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and 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, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031 unless additional congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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 Biden administration and Congress may pursue significant changes to the current healthcare laws. 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. In addition, changes in healthcare policy could

increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

***Legal, political and economic uncertainty surrounding the 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.***

The United Kingdom ceased to be a member state of the European Union on January 31, 2020 (commonly referred to as “Brexit”), and the transition period provided for in the withdrawal agreement entered by the United Kingdom and the European Union ended on December 31, 2020. On December 24, 2020, the United Kingdom and the European Union agreed on a trade and cooperation agreement, which became provisionally applicable on January 1, 2021 and has been formally applicable since May 1, 2021. The trade and cooperation agreement covers the general objectives and framework of the relationship between the United Kingdom and the European Union, including with respect to trade, transport, visas, judicial matters, law enforcement and security matters, and provides for continued participation in community programs and mechanisms for dispute resolution. Because the trade and cooperation agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the United Kingdom and the European Union as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

Uncertainties remain regarding the application of the terms of the trade and cooperation agreement and the other potential impacts of Brexit, and the lack of clarity about future laws and regulations as the United Kingdom determines which European Union rules and regulations to replace or replicate, 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. Possible changes to the rules and regulations relating to quality, safety and efficacy of products, clinical trials, marketing authorization, commercial sales and distribution of products could materially impact the regulatory regime with respect to products and approval of any product candidates in the United Kingdom or the European Union and we may be forced to restrict or delay efforts to sell our products or seek regulatory approval of product candidates in the United Kingdom and/or the European Union, which could negatively affect our business, financial condition and results of operations. The long-term effects of Brexit will depend on the implementation of the trade and cooperation agreement and any other 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 following the expiry of the Transition Period.

***We are subject to stringent and changing obligations related to data privacy and information security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations; reputational harm; and other adverse business impacts.***

In the ordinary course of our business, we and third parties upon which we rely may become exposed to, or collect and store sensitive data, including procedure-based information, PHI, credit card and other financial information, insurance information, and other potentially personally identifiable information.

We are subject to diverse laws and regulations relating to data privacy and information security. Our data processing activities may also subject us to numerous other data privacy and security obligations, such as external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal information by us and on our behalf. In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards by which we are legally or contractually bound to comply.

New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, in June 2018, the State of California enacted the CCPA, which went into effect on

January 1, 2020 and requires companies that process information on California residents to make new disclosures to consumers about their data collection, use and sharing practices, and allow consumers to opt out of certain data sharing with third parties. The CCPA also provides for civil penalties for violations (up to \$7,500 per violation), as well as a private right of action for certain data breaches that is expected to increase data breach litigation. Moreover, although the CCPA includes limited exceptions from its prescriptions, including exceptions for personal health information collected by covered entities or business associates subject to HIPAA, among others, the CCPA may regulate or impact our processing of personal information depending on the context. It remains unclear how this legislation will be interpreted and enforced. In addition, it is anticipated that the CPRA, effective January 1, 2023, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. The CPRA may require additional compliance investment and potential business process changes in the meantime. Other states have enacted data privacy laws. For example, Virginia passed its Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. 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 Europe have also been significantly reformed. In May 2018, the GDPR, took effect in EEA. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons, replacing data protection laws issued by each European Union member state based on the Directive 95/46/EC (“Directive”). Unlike the Directive, which needed to be transposed at a national level, the GDPR text is directly applicable in each European Union member state, resulting in a more uniform application of data privacy laws across the EU. Among other things, the GDPR sets out extensive compliance requirements, including providing detailed disclosures about how personal data is collected and processed, demonstrating that an appropriate legal basis is in place or otherwise exists to justify data processing activities; granting new rights for data subjects in regard to their personal data, as well as enhancing pre-existing rights (e.g., data subject access requests); introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; imposing limitations on retention of personal data; maintaining a record of data processing; complying with the principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit; and expanding the definition of personal data to include coded data and requiring changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our global turnover). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfers laws. For example, the GDPR increases the scrutiny of transfers of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. Notably, these requirements will regulate the transfer of personal data from our clinical trial sites located in the EEA to jurisdictions outside of the EEA. One of the primary safeguards enabling U.S. companies to import personal information from Europe had been certification to the EU-U.S. Privacy Shield. However, in July 2020, the Court of Justice of the European Union (“CJEU”) invalidated the EU-U.S. Privacy Shield. While the CJEU upheld the adequacy of the Standard Contractual Clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield) (“SCCs”), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place. Additionally, the European Commission issued new SCCs in June 2021 that

repeal and replace the previous SCCs. If we elect to rely on the new SCCs, we may be required to expend significant resources to update our contractual arrangements and to comply with such obligations. If we are unable to implement a valid compliance mechanism for cross-border personal information transfers, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal information from Europe, which could limit our ability to conduct clinical trial activities in Europe. In addition, laws in Switzerland and the United Kingdom similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. Other jurisdictions have enacted or are considering similar cross-border personal data transfer laws and local personal data residency laws, any of which could increase the cost and complexity of doing business.

Following the withdrawal of the United Kingdom from the European Union on January 31, 2020, and the expiration of the transition period, from January 1, 2021, companies have had to comply with both the GDPR and the UK GDPR, which, together with the amended United Kingdom Data Protection Act 2018 (“UK GDPR”), largely retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains unclear, and it is unclear how the United Kingdom’s data protection laws and regulations will develop in the medium to longer term. Further, the United Kingdom’s Information Commissioner’s Office (“ICO”) is in the process of finalizing the United Kingdom’s data transfer solution to legitimize data transfers from the United Kingdom to third countries. In June 2021, the European Commission adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EEA member states to the United Kingdom without additional safeguards. Additionally, in the event of a violation of the GDPR and UK GDPR affecting data subjects in both the United Kingdom and the EEA, we could be investigated by the ICO in the United Kingdom and supervisory authorities in the EEA. Compliance with the GDPR and UK GDPR is a rigorous and time-intensive process that may increase our cost of doing business in Europe or require us to put in place additional mechanisms to ensure compliance with such protection rules and will increase our responsibility and potential liability in relation to personal data that we process.

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.

Moreover, complying with the various cybersecurity or privacy laws that are applicable to us could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any failure (or perceived failure) to comply could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, and results of operations.

***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 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;
- the degree to which securities or industry analysts publish research or reports about our business;
- 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.

In addition, the trading prices for common stock of other medical device companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 pandemic has had a material adverse impact on our business, financial condition and results of operations, and may continue to impact us in the future. The extent to which the pandemic may continue to impact our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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 Select 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.

***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.***

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.

***Future sales of our common stock by existing stockholders 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, 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.

As of December 31, 2021, we had outstanding 36,931,762 shares of common stock. All of our outstanding shares are eligible for sale in the public market, other than shares and options held by directors, executive officers, and other affiliates that are subject to volume limitations under Rule 144 of the Securities Act, and various vesting agreements.

Further, as of December 31, 2021, holders of a substantial number of shares had rights, subject to certain conditions, to require us to file registration statements for the public resale of the common stock or to include such shares in registration statements that we may file on our behalf or for other stockholders.

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

Our executive officers, directors and current beneficial owners of 5% or more of our common stock beneficially own approximately 52% of our outstanding common stock as of December 31, 2021. 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 currently being sold 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.

***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 have incurred, and will continue to incur, increased costs as a public company, and our management has devoted, and will continue to devote, substantial time to compliance with our public company responsibilities and corporate governance practices.***

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select 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 have devoted, and continue to devote, a substantial amount of time to compliance with these requirements. Moreover, compliance with these rules and regulations increase our legal and financial costs and make some activities more time-consuming and costly.

***We have identified a material weakness in our internal controls over financial reporting, and if we are unable to remediate such material weakness and maintain an effective system of internal controls in the future, we may fail to timely and accurately report our financial results, experience a loss of investor confidence in the accuracy and completeness of our consolidated financial statements, incur material misstatements in our consolidated financial statements, and the market price of our common stock may be adversely affected.***

We are required to maintain internal control over financial reporting and to report any material weaknesses in those internal controls. For example, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act (“Section 404”). Our independent registered public accounting firm also needs to attest to the effectiveness of our internal control over financial reporting. We designed, implemented, and tested internal control over financial reporting required to comply with this obligation. The process of compiling the system and processing documentation necessary to perform the evaluation required under Section 404 is costly and challenging, and, in the future, we may not be able to complete our evaluation, testing, and any required remediation in a timely fashion.

We identified a material weakness in our internal control over financial reporting for the year ended December 31, 2021, related to ineffective information technology general controls in the areas of user access and segregation of duties related to certain information technology systems that support our financial reporting process specifically related to expenditures. Although these control weaknesses did not result in any material misstatement of our consolidated financial statements for the periods presented, they could lead to a material misstatement of account

balances or disclosures. Accordingly, our management had concluded that these control weaknesses constitute a material weakness. As a result, our management concluded that our internal control was not effective as of December 31, 2021. Our management, under the oversight of our Audit Committee and in consultation with outside advisors, has begun evaluating and implementing measures designed to ensure that the control deficiencies contributing to the material weakness are remediated. These remediation measures include, but are not limited to: (i) evaluating and implementing enhanced process controls around user access management; and (ii) expanding the management and governance over user access and system controls.

We believe the above actions will be effective in remediating the material weakness described above and we will continue to devote time and attention to these remedial efforts. However, as we continue to evaluate and take actions to improve our internal control over financial reporting, we may take additional actions to address control deficiencies or modify certain of the remediation measures described above. Our remediation efforts will not be considered complete until the applicable controls operate for a sufficient period of time and our management has concluded, through testing, that these controls are operating effectively.

If we are unable to remediate the material weakness timely and sufficiently or if we identify future material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion or expresses a qualified or adverse opinion about the effectiveness of our internal control over financial reporting, we may experience a loss of investor confidence in the accuracy and completeness of our consolidated financial statements, incur material misstatements in our consolidated financial statements, incur difficulty accessing capital on favorable terms, or at all, be subject to fines, penalties or judgments, incur reputational harm, and the market price of our common stock may be adversely affected. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, which could require additional financial and management resources and materially and adversely affect our business, results of operations and financial condition.

***Anti-takeover provisions in our charter documents 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 currently in effect 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 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 provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States are 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 provides 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 do 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. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such actions under the Securities Act and an investor cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims and there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of

our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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 further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.



## **ITEM 2. PROPERTIES**

Our corporate headquarters is located in Redwood City, California, where we lease and occupy approximately 50,000 square feet of office, manufacturing, and laboratory space. In addition, we lease various other office and warehouse spaces in Redwood City and Switzerland.

We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

## **ITEM 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

## **ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock has been listed on the Nasdaq Global Select Market under the symbol “LUNG” since October 1, 2020. Prior to this date, there was no public market for our common stock.

### **Holders of Common Stock**

As of February 23, 2022, there were approximately 160 holders of record of our common stock. The actual number of stockholders is greater than this number of holders of record and includes stockholders who are beneficial owners but whose shares are held in the street name by brokers and other nominees.

### **Dividend Policy**

We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and therefore we do not anticipate declaring or paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

### **Recent Sales of Unregistered Securities**

None.

### **Use of Proceeds from Initial Public Offering**

On September 30, 2020, our registration statement on Form S-1 (File No. 333-248635) relating to our initial public offering (“IPO”) of common stock became effective. There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 1, 2020.

### **Purchases of Equity Securities by the Issuer and Affiliated Purchases**

None.

**ITEM 6. RESERVED**

## ITEM 7. 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 our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Part I, Item 1A, “Risk Factors” and elsewhere in this Annual Report on Form 10-K. For the discussion of our financial condition and results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019, please refer to Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 15, 2021.*

### 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 100,000 valves used to treat more than 25,000 patients. 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. Our sales territory managers are focused on promoting awareness and increasing adoption of our solution primarily among the pulmonologists performing interventional pulmonary procedures across approximately 500 high volume hospitals in the United States. 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 APC and MS-DRG payment groupings. Current reimbursement in the United States is believed to cover the hospital costs of the procedure and related inpatient care. Commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, and BCBS Michigan 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 located 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 also store finished goods at secondary facilities. 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 the sale 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, sales and marketing activities, and investing in general and administrative infrastructure. We generated revenue of \$48.4 million, with a gross margin of 73.6% and a net loss of \$48.7 million, for the year ended December 31, 2021 compared to revenue of \$32.7 million, with a gross margin of 64.8% and a net loss of \$32.2 million, for the year ended December 31, 2020. As of December 31, 2021, we had an accumulated deficit of \$291.4 million, cash and cash equivalents and marketable securities of \$191.0 million, and \$17.4 million of outstanding term loans and credit agreements, net of debt discount and debt issuance costs.

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 to increase our addressable market and to expand 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.

Management believes that the Company's existing cash, cash equivalents and marketable securities will allow the Company to continue its operations for at least the next 12 months from the date of the issuance of our consolidated financial statements.

#### ***Impact of the COVID-19 Pandemic***

The COVID-19 pandemic has resulted in public health responses including travel bans, social distancing requirements, quarantines, stay-at-home orders and other significant measures, which have delayed clinical trials and FDA operations and adversely impacted the number of procedures performed using our products. In the markets in which we operate, elective, specialty and other procedures and appointments have been suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. As a result, we have experienced a material adverse impact on our business, financial condition and results of operations from a decrease and delay of procedures involving our products.

The COVID-19-driven impact on procedure volumes, which began in 2020, extended into the first quarter of 2021. Beginning in March 2021, we observed indicators of recovery in our U.S. markets which continued through the second quarter. During the third quarter of 2021, procedure volumes were adversely impacted by the Delta variant of COVID-19 in certain regions of the U.S. During the fourth quarter of 2021, sales increased in regions of the U.S. less affected by COVID-19, which were partially offset by decreased sales in U.S. regions significantly impacted by the Delta and Omicron variants of COVID-19. In international markets, our business faced continued pressure in the fourth quarter of 2021 as a result of the COVID-19 surge that led to lockdowns across a number of markets in Europe. We may continue to see regional variations in procedure volumes in our U.S. and international markets

from the COVID-19 pandemic and its variants. We are encouraged for the longer term, and we believe the following key indicators are contributing to the stabilization of our business:

- continued opening of new accounts;
- strong physician participation in virtual trainings;
- a strong patient pipeline evidenced by an increase in StratX report activity, a rebound in patient calls into hospitals inquiring about our procedure, and a resumption of patient calls to our reimbursement support service; and
- hospitals and centers accepting patients for elective procedures.

In response to the COVID-19 pandemic, we implemented a variety of measures intended to help us manage through the impact of the pandemic and position us to resume operations quickly and efficiently as restrictions, recommendations, and best practices evolve. These measures have included, and continue to include:

- establishing safety protocols, facility enhancements, and work-from-home strategies to protect our employees;
- ensuring that our manufacturing and supply chain operations remain intact and operational, and building over four months of inventory;
- keeping our workforce intact and continuing to build our team, including expansion of our U.S. sales force;
- continuing to focus on new account openings and implementing virtual physician and sales force training programs;
- accelerating our physician education programs and direct-to-patient marketing efforts through social media or other virtual forums;
- increasing our capital base by \$201.4 million through our IPO in October 2020; and
- continuing to invest in research and development activities in order to advance our AeriSeal clinical programs.

Despite signs of recovery of our business, we cannot be certain that any recovery will be sustained, or that a further resurgence of COVID-19 or variants of the virus will not occur. The measures adopted in response to, and challenges resulting from, the COVID-19 pandemic may continue to adversely affect our employees, including our sales force, hospitals, physicians, patients, communities and business operations, and may continue to contribute to significant volatility and negative pressure on the U.S. and world economy and financial markets.

Further, we cannot assure you that our recent volume of Zephyr Valves sold are indicative of future results. The number of Zephyr Valves sold in the future may decrease due to a resurgence of the COVID-19 pandemic. In addition, there may be limited provider capacity due to labor shortages, or for other reasons, which could limit the ability of patients to receive treatment with Zephyr Valves. Limited provider and hospital capacity has had a material adverse effect on our business, financial condition and results of operations and may continue to materially adversely affect us even as the pandemic subsides.

The extent to which the COVID-19 pandemic impacts our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and variant strains, governmental and societal response to contain and treat COVID-19 and variant strains, and the availability and distribution of vaccines and public acceptance of vaccines, among others.

Our consolidated financial statements reflect judgments and estimates that could change in the future as a result of the COVID-19 pandemic. For more information regarding these risks and potential impacts, please refer to Part I, Item 1A, “Risk Factors.”

### **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 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 30% have managed Medicare/Medicaid and the remaining 45% 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. Commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, and BCBS Michigan have issued positive coverage policies for the Zephyr Valve, and United Healthcare no longer considers the procedure unproven or experimental. Some commercial payors 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 more established operating histories, established relationships with pulmonologists who commonly treat patients with emphysema, significantly greater name recognition, widespread distribution channel, 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 are conducting 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 substantially 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 years ended December 31, 2021 and 2020.

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 of facilities overhead cost, including rent and utilities. Cost of goods sold also includes 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 expenses related to stock-based compensation for employees engaged in research and development, consulting services, clinical trial expenses, regulatory expenses, prototyping, testing, laboratory supplies, 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 variable sales 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 our sales and marketing spending to generate sales opportunities. We expect expenses to increase in absolute dollars as we 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 facilities 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 SEC requirements, director and officer insurance premiums and investor relations costs. We also saw an increase in our stock-based compensation expense with the establishment of our new equity plan 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. Interest income is predominantly derived from investing surplus cash in money market funds and marketable securities.

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

Other income (expense), net primarily consists of changes in the fair value of our derivative liabilities, changes in the fair value of preferred stock warrants and foreign currency exchange gains and losses. In February 2020, the warrants were partly exercised and partly expired. The final fair value of the warrant liability was reclassified to stockholders' equity/(deficit). All of our derivative liabilities were settled during 2020. Upon the closing of our IPO on October 5, 2020, we paid \$1.9 million pursuant to the Success Fee Agreement to Oxford Finance LLC. In connection with the closing of our IPO, the 2020 Notes were converted into 2,561,484 shares of common stock.

## Results of Operations:

### Comparison of the Years Ended December 31, 2021 and December 31, 2020

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

	Year Ended December 31,		\$ Change	% Change
	2021	2020		
	(in thousands)			
Revenue	\$ 48,416	\$ 32,733	\$ 15,683	47.9 %
Costs of goods sold	12,786	11,531	1,255	10.9 %
Gross profit	35,630	21,202	14,428	68.1 %
Operating expenses:				
Research and development	13,063	7,460	5,603	75.1 %
Selling, general and administrative	69,871	46,074	23,797	51.6 %
Total operating expenses	82,934	53,534	29,400	54.9 %
Loss from operations	(47,304)	(32,332)	(14,972)	46.3 %
Interest income	400	213	187	87.8 %
Interest expense	(829)	(3,181)	2,352	(73.9)%
Other income (expense), net	(585)	3,282	(3,867)	(117.8)%
Net loss before tax	(48,318)	(32,018)	(16,300)	50.9 %
Income tax expense	343	213	130	61.0 %
Net loss	\$ (48,661)	\$ (32,231)	\$ (16,430)	51.0 %

### Revenue

Revenue increased by \$15.7 million, or 47.9%, to \$48.4 million during the year ended December 31, 2021, compared to \$32.7 million during the year ended December 31, 2020. Revenue from the sale of products in the United States increased by \$8.8 million, to \$25.0 million, during the year ended December 31, 2021, compared to \$16.2 million during the year ended December 31, 2020 and an increase in the sale of products in the international markets of \$6.9 million, to \$23.4 million, compared to \$16.5 million during the year ended December 31, 2020. The increase in revenue was driven by increased sales of the Zephyr Valve as we gradually recovered from the global COVID-19 pandemic and continued to expand commercialization efforts.

### Cost of Goods Sold and Gross Margin

Cost of goods sold increased by \$1.3 million, or 10.9%, to \$12.8 million during the year ended December 31, 2021, compared to \$11.5 million during the year ended December 31, 2020. The increase was mainly due to increased number of products sold, increased manufacturing costs as we expanded headcount and invested in operational infrastructure to support anticipated future growth. Cost of goods sold for the year ended December 31, 2020 was also impacted by lower manufacturing utilization in the second quarter of 2020 resulting from the response to the COVID-19 pandemic. The increase in procedure volumes and improved operating leverage caused gross margin to increase from 65% during the year ended December 31, 2020 to 74% during the year ended December 31, 2021.

### Research and Development Expenses

Research and development expenses increased by \$5.6 million, or 75.1%, to \$13.1 million during the year ended December 31, 2021, compared to \$7.5 million during the year ended December 31, 2020. The increase in research and development expenses was primarily due to an increase of \$1.7 million in personnel expenses including stock-based compensation as we expanded our research and development team, an increase of \$2.8 million in costs

associated with our clinical trials, including fees paid to contract research organizations and testing expenses, and an increase of \$1.1 million in professional services, regulatory, facility and other expenses during the year ended December 31, 2021.

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

Selling, general and administrative expenses increased by \$23.8 million, or 51.6%, to \$69.9 million during the year ended December 31, 2021 compared to \$46.1 million during the year ended December 31, 2020. This increase in selling, general and administrative expenses was primarily due to an increase of \$16.7 million of payroll and personnel-related expenses including stock based compensation as we expanded our sales and marketing and administrative function, an increase of \$4.0 million in advertising expenses, an increase of \$2.1 million in insurance costs associated with being a public company, an increase of \$1.9 million in consulting expenses, and an increase of \$2.1 million in facility and other expenses, offset by a decrease of \$3.0 million resulting from the write-off of deferred initial public offering costs in the second quarter of 2020.

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

Interest expense decreased by \$2.4 million, or 73.9%, to \$0.8 million during the year ended December 31, 2021, compared to \$3.2 million during the year ended December 31, 2020 primarily due to payoff of the Oxford Term Loan, conversion of the 2020 Notes into common shares upon IPO in 2020, offset by borrowings under the CIBC Loan. Interest income increased by \$0.2 million for the year ended December 31, 2021 compared to the year ended December 31, 2020, which was primarily due to increased marketable securities balances in 2021 compared to 2020.

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

Other income (expense), net decreased by \$3.9 million to (\$0.6) million during the year ended December 31, 2021, compared to \$3.3 million during the year ended December 31, 2020, primarily related to the closing of our IPO in 2020 leading to favorable fair value adjustments of derivative liabilities in 2020.

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

To date, we have financed our operations primarily through initial public offering, private placements of equity securities, debt financing arrangements and sales of our products. As of December 31, 2021, we had cash and cash equivalents and marketable securities of \$191.0 million, an accumulated deficit of \$291.4 million, and \$16.9 million outstanding under the CIBC Loan, net of debt discount.

### ***Term Loan***

#### ***Oxford Finance Loan***

From August 2014 until February 2020, the Company was party to a Loan and Security Agreement with Oxford Finance LLC, which provided the ability to borrow up to \$20.0 million in term loans (“Oxford Finance Loan”). In 2014, the Company borrowed \$15.0 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 8.5% of the term loan amount was due at maturity and was being accreted using the effective interest rate method. The term loan was collateralized by assets, including cash and cash equivalents, accounts receivable and property and equipment. The Oxford Finance Loan was subsequently amended in 2017 and 2018 to extend the interest only period and to extend the maturity date to July 1, 2020, and at the Company’s option, further extend the maturity date to May 1, 2021. In 2019, the Company elected to extend the maturity date to May 2021.

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 was required to pay up to \$2.5 million (the “Success Fee”) to Oxford Finance

LLC, the amount of which would be based on actual borrowings, up to \$20.0 million. This agreement was identified as a freestanding derivative under ASC 815, *Derivatives* and was 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 statements of operations and comprehensive loss (Note 4). On October 5, 2020, in connection with the IPO, the Company paid \$1.9 million pursuant to the Success Fee Agreement to Oxford Finance LLC based on the \$15.0 million borrowed.

On February 20, 2020, the Company repaid its entire obligation under the term loan agreement with Oxford Finance LLC amounting to \$17.3 million, including outstanding loan amount of \$15.0 million, final payment of \$1.3 million, amendment fees of \$0.9 million and accrued interest of \$0.1 million. The repayment of the obligation under the term loan agreement with Oxford Finance LLC was accounted as extinguishment and the Company recorded a loss on extinguishment of \$0.4 million included in interest expense in the consolidated statements of operations and comprehensive loss.

In 2020, the Company recorded interest expense related to deferred financing and debt issuance costs of less than \$0.1 million, respectively.

Interest expense on the term loan amounted to \$0.4 million during the years ended December 31, 2020.

#### *CIBC Loan*

On February 20, 2020, the Company executed a Loan and Security Agreement (the “CIBC Agreement”) with Canadian Imperial Bank of Commerce (“CIBC”) to raise up to \$32.0 million in debt financing (“CIBC Loan”) consisting of \$17.0 million advanced at the closing of the agreement (“Tranche A”), with the option to drawing up to an additional \$8.0 million (“Tranche B”) on or before February 20, 2022. The term loan also provides for an additional financing tranche (“Tranche C”) of up to \$7.0 million on or prior to February 20, 2022, which was conditioned upon achieving a trailing six-month revenue of at least \$20.0 million as of the date of any Tranche C borrowing. The availability of Tranche B and Tranche C is further conditioned upon the joining of Pulmonx International Sàrl to the CIBC Agreement and the execution by Pulmonx International Sàrl of Swiss-law collateral documentation in favor of CIBC. The CIBC Loan originally had a five-year term maturing on February 20, 2025, which included 24 months of interest only payments followed by 36 months of equal payments of principal and interest. The interest only period can be extended to 36 months if the Company achieves three-month trailing revenue of at least \$20.0 million as of February 20, 2022. The CIBC Loan bears interest at a floating rate equal to 1.0% above the Wall Street Journal Prime Rate at any time. The Tranche C loan will bear interest at a floating rate equal to 1.5% above the Wall Street Journal Prime Rate at any time. The CIBC Loan is collateralized by substantially all of the Company’s assets, including cash and cash equivalents, accounts receivable, intellectual property and equipment. The Company may prepay the loan, subject to certain requirements. The CIBC Agreement includes customary restrictive covenants, financial covenants, events of default and other customary terms and conditions.

In April 2020, the Company entered into a First Amendment to CIBC Agreement that changed the maturity date to March 15, 2022, which would be automatically extended to February 20, 2025 if the maturity of all outstanding convertible notes was extended to a date no earlier than May 21, 2025 or all convertible notes converted into convertible preferred stock of the Company. An amendment fee of \$0.2 million was paid. The Tranche B drawing is conditioned to achieving a trailing six-month revenue of at least \$15.0 million as of the date of any Tranche B borrowing. On the date of drawing Tranche B Loan or Tranche C Loan, the Company will pay a structuring fee in an amount equal to 1.0% of the amount of Tranche B Loan or Tranche C Loan. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In December 2020, to address certain post-close covenants for which the Company was not in compliance, the Company entered into a Second Amendment to the CIBC Agreement that extended the compliance date for certain post-close covenants to June 30, 2021.

In March 2021, the Company entered into an Amended and Restated Agreement which extended the maturity date from March 15, 2022 to February 20, 2025, and modified certain financial covenants. Per the amended terms, 36 equal payments of principal plus accrued interest will be due beginning March 31, 2022. The beginning of principal repayment can be extended to March 31, 2023 if the Company achieves three-month trailing revenue of at least \$20.0 million as of February 20, 2022. In connection with the Amended and Restated Agreement, the Company paid fees to CIBC of less than \$0.1 million which were recorded as a discount on the CIBC Loan and are being accreted over the life of the term loan using the effective interest method. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In June 2021, the Company entered into a First Amendment to Amended and Restated Loan and Security Agreement with CIBC that extended the compliance of certain post-close covenants to March 31, 2022.

In October 2021, the Company entered into a Second Amendment to the Amended and Restated Loan and Security Agreement with CIBC, which extended the interest only period of the loan from 24 months to 36 months. Under the amended terms, principal repayment will begin in February 2023. There was no change to the loan interest rate or maturity date.

As of December 31, 2021, the CIBC Loan had an annual effective interest rate of 4.71% per year.

The financial covenants in the CIBC Agreement require that, when the cash and cash equivalents of the Company is less than \$100.0 million, the Company have revenue for the trailing three-month period ending on the last day of each fiscal quarter of not less than 80.0% of the revenue for the trailing three-month period, as set forth in the annual projections delivered to the CIBC. Further, the Company is required to maintain unrestricted cash in an aggregate amount equal to or greater than the Adjusted EBITDA loss as defined in the CIBC Agreement for the four-month period ending on any date of determination. As of December 31, 2021, the Company was in compliance with all covenants contained in CIBC Agreement.

The Company paid \$0.4 million fees to the lender and third parties, which is reflected as a discount on the CIBC Loan and is being accreted over the life of the term loan using the effective interest method.

During the year ended December 31, 2021 and December 31, 2020, the Company recorded interest expense related to debt discount and debt issuance costs of CIBC Loan of \$0.1 million and \$0.1 million, respectively.

Interest expense on the CIBC Loan amounted \$0.8 million and \$0.7 million during the year ended December 31, 2021 and December 31, 2020, respectively.

## **2020 Notes**

In April 2020, the Company entered into a Note Purchase Agreement and Convertible Promissory Notes (collectively the “2020 Notes Agreement”) with certain investors (the “Lenders”) to issue convertible promissory notes (the “2020 Notes”) for a maximum aggregate amount of \$66.0 million. In April 2020, the Company received \$33.0 million in gross proceeds from issuance of the 2020 Notes. Upon meeting customary closing conditions, the Company can draw up to an additional \$33.0 million, provided that any such draw be for no less than \$5.0 million on or prior to April 17, 2022. All unpaid interest and principal will be due and payable upon request of the majority of Lenders (“Majority Holders”) on or after the earlier of April 17, 2022 or an event of default. The 2020 Notes accrue interest at a rate equal to 2.0% above the Wall Street Journal Prime Rate. The Company may prepay the 2020 Notes prior to April 17, 2022 only with the consent of the Majority Holders.

The 2020 Notes included embedded derivatives that were required to be bifurcated from the 2020 Notes and accounted for separately as a single, compound embedded derivative instrument under ASC 815, *Derivatives* (“2020 Notes derivative liability”). The Company determined that a share settled redemption in the case of a financing or an IPO as described in the 2020 Notes represented an embedded derivative that was not clearly and closely related to the debt host and had accounted for these settlement alternatives as separate embedded derivative liability. The fair value of the 2020 Notes derivative liability of \$3.9 million was recorded on the issuance date of the 2020 Notes

resulting in a debt discount, which was reported as a direct deduction from the face amount of the 2020 Notes. The 2020 Notes derivative liability was remeasured to its fair value at the end of each reporting period and any change in fair value is recognized in other income (expense), net in the statements of operations and comprehensive loss (Note 4). The change in fair value of \$3.9 million during the year ended December 31, 2020 was recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

Upon the closing of the IPO in October 2020, the \$33.0 million aggregate outstanding principal amount and \$0.8 million accrued interest of the 2020 Notes converted into 2,561,484 shares of common stock pursuant to the Qualified IPO conversion at the \$13.20 per share fixed price. The Company determined that the 2020 Notes derivative liability had no value upon the closing of the IPO, because value of the notes with and without such derivative was the same.

The Company incurred debt issuance costs of \$0.1 million in connection with the 2020 Notes Agreement, which were reported on the balance sheet as a direct deduction from the face amount of the 2020 Notes.

During the year ended December 31, 2020, the Company recorded interest expense of \$1.6 million on the 2020 Notes, consisting of \$0.8 million of contractual interest expense and \$0.8 million amortization of debt discount and debt issuance costs. Before the conversion upon the IPO, the 2020 Notes had an annual effective interest rate of 12.33% per year.

At December 31, 2021, the Company retained the ability to draw up to an additional \$33.0 million under the 2020 Notes Agreement until the maturity date in April 2022. The Company's obligations with respect to the 2020 Notes are unsecured and subordinated to its obligations with respect to the CIBC Loan. The 2020 Notes have customary events of default.

### **Credit Agreement**

In April 2020, Pulmonx International Sàrl, a wholly owned subsidiary of the Company, entered into a COVID-19 Credit Agreement with UBS Switzerland AG to receive up to 0.5 million Swiss Francs (\$0.5 million U.S. dollar equivalent) under Swiss Federal Government program to mitigate the economic impact of the spread of the coronavirus. In May 2020, Pulmonx International Sàrl received 0.5 million Swiss Francs (\$0.5 million U.S. dollar equivalent) under the COVID-19 Credit Agreement. The COVID-19 Credit Agreement will bear no interest and is payable within 60 months after receipt of funds. As of December 31, 2021, Pulmonx International Sàrl did not make any repayment of credit agreement. The COVID-19 Credit Agreement bears no interest and will be repaid in twelve equal installments, paid semi-annually, beginning in March of 2022.

### **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>2021</b>	<b>2020</b>
	<b>(in thousands)</b>	
<b>Net cash (used in) provided by:</b>		
Operating activities	\$ (41,388)	\$ (30,633)
Investing activities	(46,255)	12,694
Financing activities	4,456	234,831
Effect of exchange rate changes on cash and cash equivalents	106	133
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (83,081)</u>	<u>\$ 217,025</u>



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

Net cash used in operating activities was \$41.4 million for the year ended December 31, 2021. Cash used in operating activities was primarily a result of the net loss of \$48.7 million, an increase in accounts receivable of \$2.4 million, an increase in inventory of \$6.4 million primarily due to higher inventory levels required to support projected increase in sales, an increase in prepaid and other current assets of \$1.2 million, an increase in other assets of \$0.2 million, a decrease in lease liabilities of \$2.5 million, offset by an increase in accrued liabilities of \$4.8 million, stock based compensation expense of \$7.9 million, employee stock purchase plan expense of \$2.6 million, write-down of inventory due to obsolescence of \$1.2 million, depreciation and amortization expense of \$0.9 million, amortization of debt discount and debt issuance costs of \$0.1 million, non-cash lease expense of \$2.4 million, and decrease of deferred revenue of \$0.1 million. The increase in prepaid expenses, accrued liabilities and accounts payable is primarily due to increases in inventory and expenses related to operating as a public company and timing of payments to our vendors.

Net cash used in operating activities was \$30.6 million for the year ended December 31, 2020. Cash used in operating activities was primarily a result of the net loss of \$32.2 million, an increase in inventory of \$5.0 million primarily due to higher inventory levels required to support projected increase in sales, an increase in prepaid and other current assets of \$1.8 million, a decrease in income taxes payable of \$0.2 million, a decrease in lease liabilities of \$0.9 million, and a non-cash credit resulting from the change in the fair value of derivative liabilities of \$3.2 million due to extinguishment of derivative liability upon IPO partially offset by a decrease in accounts receivable of \$1.5 million, an increase in accrued liabilities of \$1.0 million, an increase in accounts payable of \$0.6 million, stock based compensation expense of \$3.2 million, write-down of inventory due to obsolescence of \$0.5 million, depreciation and amortization expense of \$0.5 million, amortization of debt discount and debt issuance costs of \$1.0 million, non-cash lease expense of \$1.5 million and non-cash charges for write-off of deferred offering costs of \$3.0 million as we withdrew our registration statement for our initial public offering in May 2020. The increase in prepaid expenses, accrued liabilities and accounts payable is primarily due to increases in inventory and expenses related to operating as a public company and timing of payments to our vendors.

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

Net cash provided by investing activities in the year ended December 31, 2021 was \$46.3 million primarily consisting of maturities of investments of \$10.0 million, offset by the purchases of investments of \$52.6 million, and purchases of property and equipment of \$3.7 million.

Net cash provided by investing activities for the year ended December 31, 2020 was \$12.7 million primarily consisting of maturities of short-term investments of \$13.6 million offset by purchased of property and equipment of \$0.9 million.

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

Net cash provided by financing activities in the year ended December 31, 2021 of \$4.5 million primarily relates to proceeds of \$2.6 million from issuance of common stock under the employee stock purchase plan, and proceeds of \$1.9 million from exercise of common stock options.

Net cash provided by financing activities in the year ended December 31, 2020 of \$234.8 million primarily relates to net proceeds from our initial public offering of \$201.4 million, proceeds of \$17.3 million from borrowing under the CIBC Agreement and COVID-19 Credit Agreement, net of lender fees and costs, proceeds of \$33.0 million from the issuance of 2020 Notes, net of lender fees and costs, proceeds of \$2.3 million from the exercise of warrants for Series C-1 preferred stock, and \$2.7 million proceeds from the exercise of stock options, partially offset by repayment of debt obligations of \$17.2 million under the Oxford Agreement, payment of Success Fee of \$1.9 million, payment of deferred offering costs of \$2.5 million and payment of debt issuance cost of \$0.2 million.

### ***Material Cash Requirements***

Our net cash operating expenditures were \$41.4 million in 2021 and \$30.6 million in 2020, and we intend to continue to make investments in the development of our products, including ongoing research and development programs. Our cash outflows for capital expenditures were \$3.7 million in 2021 and \$0.9 million in 2020, and we expect to incur continued expenditures in the future in support of our commercial infrastructure, sales force and other commercialization efforts. Recent and expected working and other capital requirements include amounts related to future lease payments for operating lease obligations, which totaled \$10.0 million at December 31, 2021, with \$2.7 million expected to be paid within the next 12 months, and amounts related to future long-term debt which total \$19.1 million, with \$0.8 million expected to be paid within the next 12 months. Lastly, we may 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, 2021, we had cash, cash equivalents and marketable securities of \$191.0 million. Based on our current planned operations, we expect that our cash, cash equivalents and marketable securities will enable us to fund our operating expenses for at least 12 months from the issuance of our financial statements as of and for the year ended December 31, 2021. We believe we will meet longer-term expected future cash requirements and obligations through a combination of available cash, cash equivalents and marketable securities, debt financings, and access to other public or private equity offerings. 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.

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. The adequacy of our available funds and our ability to raise any necessary additional capital to meet longer-term operating and capital 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 impact of the COVID-19 pandemic on our business;
- 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.

### **Critical Accounting Estimates**

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. 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 Annual Report on Form 10-K.

### ***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 our 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.

### ***Preferred Stock***

We record all shares of preferred stock at their respective fair values on the dates of issuance, net of issuance costs. Our 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, our 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 preferred stock to its liquidation preference because a deemed liquidation event obligating us to pay the liquidation preferences to holders of shares of 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.

### ***Derivative Instruments***

In connection with the Oxford Agreement, we entered into the Success Fee Agreement. In the event of a Liquidity Event, before the termination of the agreement on August 28, 2021, we are required to pay up to \$2.5 million 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, 2019, the maximum amount of Success Fee subject to a potential payout was \$1.9 million. This agreement has been identified as a freestanding derivative under ASC 815, *Derivatives* ("Success Fee") 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 statements of operations and comprehensive loss (see Note 4 to our consolidated financial statements).

We valued the Success Fee derivative liability based on the Success Fee amount of \$1.9 million and the probability and estimated timing of a Liquidity Event. On October 5, 2020, in connection with the IPO, we paid \$1.9 million pursuant to the Success Fee Agreement to Oxford Finance LLC.

The 2020 Notes include embedded derivatives that are required to be bifurcated from the 2020 Notes and accounted for separately as a single, compound embedded derivative instrument under ASC 815, *Derivatives* (2020 Notes derivative liability). We determined that the share settled redemption in the case of a financing or an IPO represents an embedded derivative that is not clearly and closely related to the debt host and have accounted for these

settlement alternatives as separate embedded derivative liability. The fair value of the 2020 derivative liability of \$3.9 million was recorded on the issuance date of the 2020 Notes resulting in a debt discount, which is reported as a direct deduction from the face amount of the 2020 Notes. The 2020 derivative liability is remeasured to its fair value at the end of each reporting period and any change in fair value is recognized in other income (expense), net in the statements of operations and comprehensive loss.

We valued the 2020 Notes derivative liability using the “with and without” methodology. The “with and without” methodology involves valuing the convertible note on an as is basis and then valuing the 2020 Notes without each individual embedded derivative. The difference between the value of the 2020 Notes with the embedded derivatives and the value without each individual embedded derivative equals the fair value of that embedded derivative. We used a Monte Carlo Simulation (“MCS”) to value the embedded derivatives. The first step of each simulation was to forecast our Series G-1 preferred stock price through the expiration of the 2020 Notes. In order to estimate the future share price of the Series G-1 preferred stock, we applied a “random walk” model based upon a Geometric Brownian Motion process with a constant drift.

The fair value of the 2020 Notes derivative liability was determined using the following assumptions:

	April 17 2020
Risk-free interest rate	0.2 %
Current Series G-1 convertible preferred stock value per share	\$ 0.84
Series G-1 convertible preferred stock volatility	34.4 %

Upon the closing of the IPO in October 2020, the 2020 Notes converted pursuant to a qualified initial public offering. As a result, we concluded that the 2020 Notes derivative had no value upon the closing of the IPO, because value of the notes with and without such derivative was the same.

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

We recognize compensation costs related to stock options and awards granted to employees and non-employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value of stock options, 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 optionee is required to provide service in exchange for the award, which is typically the vesting period. We account for forfeitures as they occur.

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 the 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*

Prior to the Company's IPO, 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. Specifically, we used the guideline public company analysis, which 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.

For our valuations performed in November 2019 and April 2020, we applied a weighted combination of the market approach and the income approach outlined in the Practice Aid to determine our enterprise value. Under the market approach, we used the guideline public company analysis, guideline transactions analysis and an analysis based on a recent acquisition offer. For the guideline public company and guideline transactions analysis, we identified a group of comparable public companies and recent transactions within our industry. For the comparable companies, we estimated market multiples and ratios. These multiples and ratios were then applied to our corresponding financial metrics. When selecting comparable companies, consideration was given to industry similarity, their specific products offered, financial data availability and capital structure. The income approach incorporates the use of a discounted cash flow model in which our estimated future cash flows and our residual value beyond the forecast period are discounted using an appropriately risk-adjusted weighted average cost of capital. Our forecasts used in the discounted cash flow model are based in part on strategic plans and represent our estimates based on current and forecasted business and market conditions.

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.

As of December 31, 2021, there was \$33.7 million of unrecognized compensation costs related to non-vested common stock options and restricted stock units, expected to be recognized over a weighted-average period of 3.15 years.

Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.

### ***Income Taxes***

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

Significant judgment is required to determine our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles, complex tax laws, or variances between our actual and anticipated operating results. Therefore, actual income taxes could materially vary from these estimates.

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.

### **Recent Accounting Pronouncements**

See “Recent Accounting Pronouncements” in Note 3 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

## **ITEM 7A. 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 \$148.5 million as of December 31, 2021, which consist of cash, money market funds, commercial paper and corporate bonds. We held cash in foreign banks of approximately \$4.6 million at December 31, 2021 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 \$16.9 million under the CIBC Agreement with interest rate of 4.71% as of December 31, 2021. 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 are exposed to foreign currency risks. Revenue from sales outside of the United States represented 48.4%, and 50.5% of our total revenue for the year ended December 31, 2021, and 2020, respectively. 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, 2021 by approximately \$2.3 million and \$1.6 million, respectively, with a net impact of \$0.7 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.



ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**Pulmonx Corporation**

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## Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors  
Pulmonx Corporation  
Redwood City, California

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Pulmonx Corporation (the “Company”) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders’ equity, and cash flows for the years 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, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 1, 2022 expressed an adverse opinion thereon.

### 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 audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

### Critical Audit Matter

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

### Timing of Revenue Recognition

As described in Note 2 to the consolidated financial statements, the Company’s revenue is generated from the sale of its products to distributors and hospitals in the United States and international markets. Revenue is recognized when there is an enforceable contract and the customer obtains control of promised goods or services, in an amount that reflects consideration which the entity expects to receive in exchange for those goods or services. Control is

generally transferred upon either direct shipment or hand delivery of products. The Company's consolidated revenue was \$48.4 million for the year ended December 31, 2021.

We identified the evaluation of when performance obligations have been met and the timing of revenue recognition as a critical matter. The timing of establishing a legally enforceable contract and transferring control varies depending on the fulfillment method and customary business practices. Auditing these elements involved especially challenging auditor judgment due to the manual nature of tracking these elements.

The primary procedures we performed to address this critical audit matter included:

- Reviewing the entity's revenue recognition policies and evaluating whether those policies comply with the requirements of ASC 606.
- Evaluating managements period end analysis of the timing and accuracy of transactions recognized as revenue during a short period before and after year end by tracing transactions from the general ledger into the analysis to test completeness and obtaining and inspecting underlying source documents for significant transactions.
- Evaluating on a test basis, but with increased focus on a period deemed susceptible to revenue timing errors, the timing and accuracy of transactions recognized as revenue by obtaining and inspecting underlying source documents.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2011.

San Francisco, California

March 1, 2022

**Pulmonx Corporation****Consolidated Balance Sheets****(in thousands, except share and per share amounts)**

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 148,480	\$ 231,561
Restricted cash	231	231
Short-term marketable securities	31,561	—
Accounts receivable, net	6,562	4,228
Inventory	16,285	10,741
Prepaid expenses and other current assets	4,883	3,228
Total current assets	<u>208,002</u>	<u>249,989</u>
Long-term marketable securities	10,941	—
Property and equipment, net	4,814	1,474
Goodwill	2,333	2,333
Intangible assets, net	277	400
Right of use assets	8,075	8,976
Other long-term assets	731	536
Total assets	<u>\$ 235,173</u>	<u>\$ 263,708</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 1,582	\$ 1,472
Accrued liabilities	13,366	8,651
Income taxes payable	147	94
Deferred revenue	163	71
Credit Agreement, current	91	—
Current lease liabilities	2,201	2,238
Total current liabilities	<u>17,550</u>	<u>12,526</u>
Deferred tax liability	37	62
Long-term lease liabilities	6,844	7,618
Credit agreement	455	564
Term loan	16,869	16,804
Other long-term liabilities	179	—
Total liabilities	<u>41,934</u>	<u>37,574</u>
Commitments and contingencies (Note 8)		
Stockholders' Equity		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized; 36,931,762 shares and 35,693,753 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	37	36
Additional paid-in capital	482,885	467,147
Accumulated other comprehensive income	1,712	1,685
Accumulated deficit	(291,395)	(242,734)
Total stockholders' equity	<u>193,239</u>	<u>226,134</u>
Total liabilities and stockholders' equity	<u>\$ 235,173</u>	<u>\$ 263,708</u>

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

**Pulmonx Corporation****Consolidated Statements of Operations and Comprehensive Loss****(in thousands, except share and per share amounts)**

	Years Ended December 31,	
	2021	2020
Revenue	\$ 48,416	\$ 32,733
Cost of goods sold	12,786	11,531
Gross profit	35,630	21,202
Operating expenses		
Research and development	13,063	7,460
Selling, general and administrative	69,871	46,074
Total operating expenses	82,934	53,534
Loss from operations	(47,304)	(32,332)
Interest income	400	213
Interest expense	(829)	(3,181)
Other income (expense), net	(585)	3,282
Net loss before tax	(48,318)	(32,018)
Income tax expense	343	213
Net loss	(48,661)	(32,231)
Other comprehensive income		
Currency translation adjustment	51	318
Change in unrealized (losses) gains on marketable securities	(24)	(6)
Total other comprehensive income	27	312
Comprehensive loss	\$ (48,634)	\$ (31,919)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.35)	\$ (3.16)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,129,409	10,184,841

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

**Pulmonx Corporation**

**Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
<b>Balances at January 1, 2020</b>	17,583,150	\$ 205,339	2,100,203	\$ 2	\$ 21,750	\$ 1,373	\$ (210,503)	\$ (187,378)
Issuance of Series C-1 convertible preferred stock upon exercise of warrants	213,876	2,260	—	—	—	—	—	—
Conversion of convertible preferred stock into common stock	(17,797,026)	(207,599)	17,797,026	18	207,581	—	—	207,599
Conversion of 2020 Notes into common stock	—	—	2,561,484	3	30,589	—	—	30,592
Issuance of common stock upon initial public offering, net of issuance costs and underwriting discount of \$17,108	—	—	11,500,000	11	201,381	—	—	201,392
Issuance of common stock upon exercise of stock options	—	—	1,745,040	2	2,703	—	—	2,705
Repurchase of early exercised common stock options	—	—	(10,000)	—	—	—	—	—
Change in shares subject to repurchase	—	—	—	—	(346)	—	—	(346)
Stock-based compensation expense	—	—	—	—	3,489	—	—	3,489
Currency translation adjustment	—	—	—	—	—	318	—	318
Change in unrealized losses on marketable securities	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	(32,231)	(32,231)
<b>Balances at December 31, 2020</b>	—	—	35,693,753	36	467,147	1,685	(242,734)	226,134
Issuance of common stock upon vesting of restricted stock unit	—	—	40,908	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	1,065,567	1	1,880	—	—	1,881
Repurchase of early exercised common stock options	—	—	(12,945)	—	—	—	—	—
Change in shares subject to repurchase	—	—	—	—	204	—	—	204
Issuance of shares pursuant to Employee Stock Purchase Plan	—	—	144,479	—	2,652	—	—	2,652
Stock-based compensation expense	—	—	—	—	11,002	—	—	11,002
Currency translation adjustment	—	—	—	—	—	51	—	51
Change in unrealized losses on marketable securities	—	—	—	—	—	(24)	—	(24)
Net loss	—	—	—	—	—	—	(48,661)	(48,661)
<b>Balances at December 31, 2021</b>	—	\$ —	36,931,762	\$ 37	\$ 482,885	\$ 1,712	\$ (291,395)	\$ 193,239

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

**Pulmonx Corporation**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Years Ended December 31,	
	2021	2020
<b>Cash flows from operating activities</b>		
Net loss	\$ (48,661)	\$ (32,231)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	10,530	3,197
Change in fair value of derivative liability	—	(3,190)
Write-off of fixed assets	7	—
Allowance for doubtful accounts	4	(7)
Inventory write-downs	1,186	472
Depreciation and amortization expense	867	483
Amortization of debt discount and debt issuance costs	106	968
Write-off of deferred offering costs	—	3,030
Amortization of premiums and discounts on short-term marketable securities	59	(35)
Non-cash lease expense	2,360	1,467
<b>Net changes in operating assets and liabilities:</b>		
Accounts receivable	(2,432)	1,457
Inventory	(6,458)	(5,047)
Prepaid expenses and other current assets	(1,214)	(1,756)
Other assets	(221)	65
Accounts payable	87	592
Accrued liabilities	4,800	1,019
Income taxes payable	21	(155)
Lease liabilities	(2,517)	(876)
Deferred tax liability	(6)	22
Deferred revenue	94	(108)
Net cash used in operating activities	(41,388)	(30,633)
<b>Cash flows from investing activities</b>		
Purchases of investments	(52,584)	—
Maturities of investments	10,000	13,605
Purchases of property and equipment	(3,671)	(911)
Net cash provided by (used in) investing activities	(46,255)	12,694
<b>Cash flows from financing activities</b>		
Proceeds from borrowing under term loans, net of payment of lender fees and costs	—	17,291
Repayment of term loans	—	(17,248)
Payment of Success Fee	—	(1,875)
Proceeds from the issuance of convertible note, net of payment of lender fees and costs (includes \$0 and \$0 from related party for the years ended December 31, 2021 and 2020, respectively)	—	32,950
Proceeds from Paycheck Protection Program loan	—	2,666
Repayment of Paycheck Protection Program loan	—	(2,666)
Debt issuance cost	(41)	(162)
Payments of deferred offering costs	—	(2,462)
Proceeds from exercise of warrants for Series C-1 convertible preferred stock	—	2,261
Proceeds from exercise of common stock options	1,871	2,705
Proceeds from issuance of common stock under the employee stock purchase plan	2,652	—
Proceeds from initial public offering, net of offering costs	—	201,392
Payments for the repurchase of early exercised common stock options	(26)	(21)
Net cash provided by financing activities	4,456	234,831

Effect of exchange rate changes on cash and cash equivalents	106	133
Net (decrease) increase in cash and cash equivalents	(83,081)	217,025
Cash and cash equivalents at beginning of year	231,792	14,767
Cash, cash equivalents and restricted cash at end of year	\$ 148,711	\$ 231,792
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets:		
Cash and cash equivalents	\$ 148,480	\$ 231,561
Restricted cash	231	231
Cash, cash equivalents and restricted cash in consolidated balance sheets	\$ 148,711	\$ 231,792
<b>Supplemental non-cash items:</b>		
Lapse (increase) in repurchase rights of common stock	\$ 204	\$ (346)
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 584	\$ 65
Issuance of derivative instrument related to convertible notes	\$ —	\$ 3,900
Operating lease right of use assets obtained in exchange for new lease liabilities	\$ 1,460	\$ 3,935
Amount receivable from exercise of Options	\$ 10	\$ —
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for income taxes	\$ 322	\$ 259
Cash paid for interest	\$ 722	\$ 3,059

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



**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

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## **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 Germany, Switzerland, Australia, the United Kingdom, the Netherlands, Italy, France and Hong Kong.

### ***Initial Public Offering***

On September 30, 2020, the Company’s registration statement on Form S-1 (File No. 333-248635) relating to its initial public offering (“IPO”) of common stock became effective. The IPO closed on October 5, 2020 at which time the Company issued 11,500,000 shares of its common stock at a price of \$19.00 per share, which included the issuance of shares in connection with the exercise by the underwriters of their option to purchase up to 1,500,000 additional shares. The Company received an aggregate of \$218.5 million gross proceeds, before underwriting discounts, commissions and offering costs, and approximately \$201.4 million in net proceeds after deducting underwriting discounts and commissions and offering costs.

In addition, upon closing the IPO, all outstanding shares of the Company’s convertible preferred stock converted into 17,797,026 shares of common stock. Additionally, the \$33.0 million aggregate outstanding principal amount and \$0.8 million accrued interest of the 2020 Notes converted into 2,561,484 shares of common stock at a conversion price of \$13.20 per share. In connection with the completion of its IPO, on October 5, 2020, the Company’s certificate of incorporation was amended and restated to provide for 200,000,000 authorized shares of common stock with a par value of \$0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of \$0.001 per share.

### ***Liquidity and Going Concern***

The Company has incurred operating losses and negative cash flows from operations to date and has an accumulated deficit of \$291.4 million as of December 31, 2021. During the years ended December 31, 2021, and 2020, the Company used \$41.4 million, and \$30.6 million of cash in its operating activities, respectively. As of December 31, 2021, the Company had cash, cash equivalents and marketable securities of \$191.0 million. Historically, the Company’s activities have been financed through private placements of equity securities, debt and sale of common stock in the IPO.

The Company’s consolidated financial statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Management believes that the Company’s existing cash, cash equivalents and marketable securities will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these consolidated financial statements.

### ***Impact of the COVID-19 Pandemic***

The COVID-19 pandemic has resulted in public health responses including travel bans, social distancing requirements, quarantines, stay-at-home orders and other significant measures, which have delayed clinical trials and FDA operations and adversely impacted the number of procedures performed using our products. In the markets in which we operate, elective, specialty and other procedures and appointments have been suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. As a result, we have

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

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experienced a material adverse impact on our business, financial condition and results of operations from a decrease and delay of procedures involving our products.

The COVID-19-driven impact on procedure volumes, which began in 2020, extended throughout 2021. At the start of 2021, procedure volumes in our U.S. and international markets were adversely impacted by a winter COVID surge. Beginning in March 2021, we observed indicators of recovery in our U.S. markets which continued through the second quarter. During the third quarter of 2021, procedure volumes were adversely impacted by the Delta variant of COVID-19 in certain regions of the U.S. During the fourth quarter of 2021, procedure volumes were again adversely impacted in certain regions of the U.S. and Europe by the Delta and Omicron variants; however, we experienced some recovery in certain of our other U.S. markets. We may continue to see regional variations in procedure volumes in our US and international markets from the COVID-19 pandemic and its variants.

The Company's consolidated financial statements reflect judgments and estimates that could change in the future as a result of the COVID-19 pandemic. The COVID-19 pandemic has adversely impacted the Company's business, financial condition and results of operations by decreasing and delaying procedures performed using its products. While many regions begin to stabilize with improvements in procedure volumes, there continues to be variability and uncertainty as variants of the virus emerge. The Company can make no assurance regarding any future level of demand for the Company's products, and COVID-19 may adversely impact the results of operations and financial condition.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

### ***Reverse Stock Split***

On September 22, 2020, the Company effected a 1-for-10 reverse stock split of the Company's common stock and convertible preferred stock. The par value and authorized shares of common stock were not adjusted as a result of the reverse stock split. All issued and outstanding common stock, convertible preferred stock, stock options and per share amounts contained in the accompanying financial statements and notes to the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

### ***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 inventories, the recoverability of long-term assets, valuation of equity instruments and equity-linked instruments, valuation of common stock, stock-

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

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based compensation, derivative liabilities, 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 derivative liabilities were 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 approximates their fair value. The fair value of marketable debt securities is estimated using Level 2 inputs based on their quoted market values (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, commercial paper and corporate bonds.

***Restricted Cash***

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash for years ended December 31, 2021 and December 31, 2020 consists of collateral for letters of credit issued in connection with the real estate lease in Redwood City, California.

***Marketable Securities***

The Company determines the appropriate classification of its investments in marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company has classified and accounted for its marketable securities as available-for-sale. After consideration of the Company's risk versus reward objectives and liquidity requirements, the Company may sell these securities prior to their stated maturities. As the Company views these securities as available to support current operations, the Company classifies highly liquid securities with original maturities greater than three months at the time of purchase as short-term marketable securities and those with original maturities greater than twelve months at the time of purchase as long-term marketable securities on the balance sheet. These securities are carried at fair value as determined based upon quoted market prices or pricing models for similar securities. Unrealized gains and losses on available for sale debt securities, if any, are excluded from earnings and are reported as a component of accumulated other comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the statements of operations and comprehensive loss. Realized gains and losses, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income. There were \$31.6 million and \$10.9 million short-term and long-term marketable securities as of December 31, 2021, respectively. The Company did not identify any of its marketable securities as other-than-temporarily impaired as of December 31, 2021. There were no marketable securities as of December 31, 2020.

***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. As of December 31, 2021 and 2020, the Company also had cash on deposit with foreign banks of approximately \$4.6 million and \$5.6 million, respectively, that was not federally insured.

The Company earns revenue from the sale of its products to distributors and other customers such as hospitals. Sales of Zephyr Valves and delivery catheters accounted for most of our revenue for the years ended December 31, 2021,

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

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and 2020. 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, 2021 and 2020, no customer or distributor accounted for more than 10% of accounts receivable. For the years ended December 31, 2021 and 2020, no customer or distributor accounted for more than 10% of revenue.

The Company relies on single source suppliers for 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.

#### **Deferred Offering Costs**

Deferred offering costs, consisting of legal, accounting and other fees and costs relating to the Company's IPO, are capitalized and recorded on the balance sheet. As of December 31, 2019, \$1.6 million of deferred offering costs were recorded on the consolidated balance sheet. During the year ended December 31, 2020, the Company wrote off deferred offering costs of \$3.0 million as, in May 2020, the Company withdrew its registration statement that was filed with the SEC in February 2020. After the registration statement was withdrawn in May 2020, an additional \$1.8 million in deferred offering costs were incurred related to the Company's October 2020 IPO. In connection with the IPO, all deferred offering costs incurred after May 2020 were recorded as reduction of the gross proceeds from the IPO in the additional paid-in capital on the accompanying balance sheet as of December 31, 2020. There were no deferred offering costs capitalized as of December 31, 2021 and December 31, 2020.

#### **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, 2021 and December 31, 2020, accounts receivable is presented net of an allowance for doubtful accounts of less than \$0.1 million and \$0, respectively.

#### **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.

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

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**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 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. Prior to performing the impairment test, the Company assesses qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that the fair value of the Reporting Unit was less than the carrying amount. If after assessing the totality of events or circumstances, the Company were to determine that it is more likely than not that the fair value of the Reporting Unit is less than the carrying amount, then the Company would perform a quantitative impairment test. The quantitative impairment test involves comparing the fair value of the Reporting Unit to the carrying value. If the fair value of the Reporting Unit exceeds the carrying value of the net assets, goodwill is not impaired, and no further testing is required. If the fair value of the Reporting Unit is less than the carrying value, the Company measures the amount of impairment loss, if any, as the excess of the carrying value over the fair value of the Reporting Unit. 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 assets.

**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 vehicles and meets the requirements to account for these leases as operating leases. The Company recognizes rent expense on a straight-line basis over the non-cancelable lease term. 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.

Upon adoption of ASC 842, Leases, on January 1, 2019, the Company determined if an arrangement is a lease, or contains a lease, at inception. The asset component of the Company's operating leases is recorded as right-of-use assets, and the liability component is recorded as current lease liabilities and long-term lease liabilities in the Company's consolidated balance sheets. As of December 31, 2021 and 2020, the Company did not record any finance leases. ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate, which is the estimated rate the Company would be

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required to pay for a fully collateralized borrowing equal to the total lease payments over the term of the lease, to determine the present value of future minimum lease payments. The ROU asset also includes any lease payments made to the lessor at or before the commencement date, minus lease incentives received, and initial direct costs incurred. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASC 842, the Company combines lease and non-lease components. Variable lease payments are expenses as incurred.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

### ***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.

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

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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 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 is disclosed in Note 12, "Segment Information".

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 and 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 expenses 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 \$5.1 million and \$1.5 million for the years ended December 31, 2021 and 2020, respectively.

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**Foreign Currency Translation and Transaction Gains and Losses**

The functional currencies of the Company's wholly owned subsidiaries in Switzerland, Germany, Australia, the United Kingdom, France 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 statements of operations and comprehensive loss and was \$0.1 million and \$0.3 million during the years ended December 31, 2021 and 2020, respectively.

Foreign currency transaction gains and losses are included in other income (expense), net in the consolidated statements of operations and comprehensive loss and was \$(0.6) million and \$0.1 million during the years ended December 31, 2021 and 2020, respectively.

**Stock-Based Compensation**

The Company accounts for stock-based compensation arrangements with employees and non-employees in accordance with ASC 718, *Compensation—Stock Compensation*, using a fair-value based method. The Company determines the fair value of all stock options and the 2020 Employee Share Purchase Plan ("ESPP") awards on the date of grant using the Black-Scholes option pricing model. The Company's determination of the fair value 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, if applicable, is recognized over the requisite service period using the graded vesting method. The Company accounts for forfeitures as they occur.

The Company issued stock options in exchange for the receipt of goods or services from non-employees. Costs for such equity instruments are measured at the fair value of the equity instruments issued on the measurement date as the Company believes that the fair value of the equity instrument is more reliably measured than the fair value of the services received.

**Fair Value of Common Stock**

Prior to the Company's IPO, the fair value of the Company's common stock was determined by the board of directors with assistance from management and external appraisers. Management's approach to estimate the fair value of the Company's common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* ("Practice Aid"). Management considered several factors to estimate enterprise value, including significant milestones that would generally contribute to increases in the value of the common stock. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.



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**Income Taxes**

The Company accounts for income taxes under the asset and 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 and convertible preferred stock warrants 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 and unrealized gains and losses from marketable securities are the components of other comprehensive loss that are excluded from the reported net loss for all periods presented.

**3. Recent Accounting Pronouncements****Recently Adopted Accounting Pronouncements**

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This ASU is effective for public business entities for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company adopted ASU 2019-12 as of January 1, 2021 and the adoption did not have a material impact on the Company's consolidated financial statements.

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**Recent Accounting Pronouncements Not Yet Adopted**

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)* (“ASU 2020-04”). The amendments in ASU 2020-04 provide optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments in ASU 2020-04 are effective for all entities as of March 12, 2020 through December 31, 2022. An entity may elect to apply the amendments for contract modifications by Topic or Industry Subtopic as of any date from the beginning an interim period that includes or is subsequent to March 12, 2020, or prospectively from the date that the financial statements are available to be issued. Once elected for a Topic or an Industry Subtopic, the amendments must be applied prospectively for all eligible contract modifications for that Topic or Industry Subtopic. The Company may elect to apply ASU 2020-04 as its contracts referenced in London Interbank Offered Rate (“LIBOR”) are impacted by reference rate reform. The Company is currently evaluating the impact of the adoption of this ASU on the Company’s consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40)—Accounting For Convertible Instruments and Contracts in an Entity’s Own Equity* (“ASU 2020-06”). ASU 2020-06 simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. ASU 2020-06 also simplifies the diluted net income per share calculation in certain areas. This ASU is effective for the Company for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years, with early adoption permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of this principle on the Company’s consolidated financial statements.

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, according to which, the new standard is effective for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies (“SRC”) as defined by the SEC, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, including the Company, 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 the Company’s consolidated financial statements.

All other newly issued accounting pronouncements not yet effective have been deemed either immaterial or not applicable.

**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—Inputs are 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 are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that

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are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

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, marketable securities and derivative liabilities.

*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 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 approximates the fair value and is classified as a Level 2 liability.

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 tables 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, 2021			Total
	Level 1	Level 2	Level 3	
<b>Assets:</b>				
Money market funds	\$ 831	\$ —	\$ —	\$ 831
Commercial paper	—	2,000	—	2,000
Corporate bonds	—	4,410	—	4,410
Cash equivalents	831	6,410	—	7,241
U.S. Government agency bonds	14,977	5,504	—	20,481
Commercial paper	—	19,107	—	19,107
Corporate bonds	—	2,914	—	2,914
Marketable securities	14,977	27,525	—	42,502
Total financial assets	\$ 15,808	\$ 33,935	\$ —	\$ 49,743

	December 31, 2020			Total
	Level 1	Level 2	Level 3	
<b>Assets:</b>				
Money market funds	\$ 10,533	\$ —	\$ —	\$ 10,533
Cash equivalents	10,533	—	—	10,533
Total financial assets	\$ 10,533	\$ —	\$ —	\$ 10,533

There were no liabilities measured at fair value on a recurring and non-recurring basis as of December 31, 2021 and December 31, 2020.

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The following table summarizes the cost, unrealized gains and losses and fair value of marketable securities (in thousands):

	December 31, 2021			
	Amortized Cost	Unrealized Losses	Unrealized Gains	Fair Value
U.S. Government agency bonds	\$ 20,509	\$ (28)	\$ —	\$ 20,481
Corporate bonds	2,915	(1)	—	2,914
Commercial paper	19,102	—	5	19,107
Marketable securities	<u>\$ 42,526</u>	<u>\$ (29)</u>	<u>\$ 5</u>	<u>\$ 42,502</u>
Amounts recognized on the consolidated balance sheet				
Short-term marketable securities				31,561
Long-term marketable securities				10,941
Marketable securities				<u>\$ 42,502</u>

As of December 31, 2021, all of the marketable securities are classified as available for sale, in which short-term marketable securities mature within one year and long-term marketable securities mature in one to two years.

At December 31, 2021, accrued interest on marketable securities of \$0.1 million was included in prepaid expenses and other current assets on the consolidated balance sheet.

The Company did not have marketable securities as of December 31, 2020.

Derivative liabilities include derivatives associated with the Company's Success Fee Agreement with Oxford Finance LLC (Note 6) and the 2020 Notes derivative liability (Note 6).

The Company valued Success Fee derivative liability based on the Success Fee amount of \$1.9 million and the probability and estimated timing of a liquidity event. The probability of occurrence of a Liquidity Event was estimated to be up to 65% before the expiration of the agreement as of December 31, 2019. Changes in the estimated probability may result in an increase or decrease in the fair value of the derivative liability. On October 5, 2020, the Success Fee derivative liability was settled upon the Company paying \$1.9 million pursuant to the Success Fee Agreement to Oxford Finance LLC.

The Company valued the 2020 Notes derivative liability using the "with and without" methodology. The "with and without" methodology involves valuing the convertible note on an as is basis and then valuing the 2020 Notes without each individual embedded derivative. The difference between the value of the 2020 Notes with the embedded derivatives and the value without each individual embedded derivative equals the fair value of that embedded derivative. In April 2020, the Company valued the embedded derivatives using a Monte Carlo Simulation ("MCS"). The first step of each simulation was to forecast the Company's Series G-1 convertible preferred stock price through the expiration of the 2020 Notes. In order to estimate the future share price of the Series G-1 convertible preferred stock, the Company applied a "random walk" model based upon a Geometric Brownian Motion process with a constant drift.

The fair value of the 2020 Notes derivative liability was determined using the following assumptions:

	April 17, 2020
Risk-free interest rate	0.2 %
Current Series G-1 convertible preferred stock value per share	\$ 0.84
Series G-1 convertible preferred stock volatility	34.4 %

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Upon the closing of the IPO in October 2020, the 2020 Notes converted pursuant to a qualified initial public offering (Note 6). As a result, the Company concluded that the 2020 Notes derivative had no value upon the closing of the IPO, because value of the notes with and without the such derivative was the same.

The change in fair value of the derivative liabilities is summarized below (in thousands):

	Success Fee Derivative Liability	2020 Notes Derivative Liability
Beginning fair value, January 1, 2020	\$ 1,165	\$ —
Fair value at inception	—	3,900
Change in fair value	710	(3,900)
Payment of Success Fee	(1,875)	—
Ending fair value, December 31, 2020	\$ —	\$ —

## 5. Balance Sheet Components

### *Cash and Cash Equivalents*

The Company's cash and cash equivalents consist of the following (in thousands):

	December 31,	
	2021	2020
Cash	\$ 141,239	\$ 221,028
Cash equivalents:		
Money market funds	831	10,533
Commercial paper	2,000	—
Corporate bonds	4,410	—
Total cash and cash equivalents	\$ 148,480	\$ 231,561

### *Inventory*

Inventory consists of the following (in thousands):

	December 31,	
	2021	2020
Raw materials	\$ 3,738	\$ 3,342
Work in process	518	227
Finished goods	12,029	7,172
Total inventory	\$ 16,285	\$ 10,741

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**Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2021	2020
Prepaid expenses	\$ 1,869	\$ 381
Prepaid insurance	2,305	2,131
VAT receivable	362	339
Other current assets	347	377
<b>Total prepaid expenses and other current assets</b>	<b>\$ 4,883</b>	<b>\$ 3,228</b>

**Property and Equipment, Net**

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2021	2020
Machinery and equipment	\$ 1,635	\$ 1,447
Computer equipment and software	1,561	1,062
Furniture and fixtures	252	229
Leasehold improvements	2,277	57
Construction in progress	1,332	452
Total	7,057	3,247
Less: accumulated depreciation	(2,243)	(1,773)
<b>Property and equipment, net</b>	<b>\$ 4,814</b>	<b>\$ 1,474</b>

Depreciation expense for the years ended December 31, 2021 and December 31, 2020 was \$0.7 million and \$0.3 million, respectively.

**Goodwill**

Goodwill was \$2.3 million as of December 31, 2021 and December 31, 2020 arising from the Company's acquisition 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 2021 and 2020. The Company performed an annual test for goodwill impairment in the fourth quarter of the fiscal years ended December 31, 2021 and December 31, 2020 and determined that goodwill was not impaired.

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**Intangible Assets**

Intangible assets consist of the following (in thousands):

	December 31, 2021		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed technology	\$ 1,658	\$ (1,410)	\$ 248
Trademarks	191	(162)	29
<b>Total intangible assets</b>	<b>\$ 1,849</b>	<b>\$ (1,572)</b>	<b>\$ 277</b>

	December 31, 2020		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed technology	\$ 1,658	\$ (1,299)	\$ 359
Trademarks	191	(150)	41
<b>Total intangible assets</b>	<b>\$ 1,849</b>	<b>\$ (1,449)</b>	<b>\$ 400</b>

Amortization expense relating to the intangibles totaled \$0.1 million during each of the years ended on December 31, 2021 and 2020.

Future amortization expense is as follows (in thousands):

Year Ending December 31,	
2022	\$ 123
2023	123
2024	31
<b>Total amortization expense</b>	<b>\$ 277</b>

**Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2021	2020
Accrued employee bonuses	\$ 4,741	\$ 2,374
Accrued vacation	1,850	1,810
Other accrued personnel related expenses	2,145	1,368
Accrued professional fees	2,420	1,313
Sales taxes, franchise tax and VAT	730	521
Liability for early exercise of stock options	399	629
Accrued inventory purchases	258	57
Other	823	579
<b>Total accrued liabilities</b>	<b>\$ 13,366</b>	<b>\$ 8,651</b>

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## **6. Long Term Debt and Convertible Notes**

### ***Term Loan***

#### *Oxford Finance Loan*

From August 2014 until February 2020, the Company was party to a Loan and Security Agreement with Oxford Finance LLC, which provided the ability to borrow up to \$20.0 million in term loans (“Oxford Finance Loan”). In 2014, the Company borrowed \$15.0 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 8.5% of the term loan amount was due at maturity and was being accreted using the effective interest rate method. The term loan was collateralized by assets, including cash and cash equivalents, accounts receivable and property and equipment. The Oxford Finance Loan was subsequently amended in 2017 and 2018 to extend the interest only period and to extend the maturity date to July 1, 2020, and at the Company’s option, further extend the maturity date to May 1, 2021. In 2019, the Company elected to extend the maturity date to May 2021.

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 was required to pay up to \$2.5 million (the “Success Fee”) to Oxford Finance LLC, the amount of which would be based on actual borrowings, up to \$20.0 million. This agreement was identified as a freestanding derivative under ASC 815, *Derivatives* (“Success Fee”) and was 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 statements of operations and comprehensive loss (Note 4). On October 5, 2020, in connection with the IPO, the Company paid \$1.9 million pursuant to the Success Fee Agreement to Oxford Finance LLC based on the \$15.0 million borrowed.

On February 20, 2020, the Company repaid its entire obligation under the term loan agreement with Oxford Finance LLC amounting to \$17.3 million, including outstanding loan amount of \$15.0 million, final payment of \$1.3 million, amendment fees of \$0.9 million and accrued interest of \$0.1 million. The repayment of the obligation under the term loan agreement with Oxford Finance LLC was accounted as extinguishment and the Company recorded a loss on extinguishment of \$0.4 million included in interest expense in the consolidated statements of operations and comprehensive loss.

In 2020, the Company recorded interest expense related to deferred financing and debt issuance costs of less than \$0.1 million, respectively.

Interest expense on the term loan amounted to \$0.4 million during the years ended December 31, 2020.

#### *CIBC Loan*

On February 20, 2020, the Company executed a Loan and Security Agreement (the “CIBC Agreement”) with Canadian Imperial Bank of Commerce (“CIBC”) to raise up to \$32.0 million in debt financing (“CIBC Loan”) consisting of \$17.0 million advanced at the closing of the agreement (Tranche A), with the option to drawing up to an additional \$8.0 million (“Tranche B”) on or before February 20, 2022. The term loan also provides for an additional financing tranche (“Tranche C”) of up to \$7.0 million on or prior to February 20, 2022, which was conditioned upon achieving a trailing six-month revenue of at least \$20.0 million as of the date of any Tranche C borrowing. The availability of Tranche B and Tranche C is further conditioned upon the joining of Pulmonx International Sàrl to the CIBC Agreement and the execution by Pulmonx International Sàrl of Swiss-law collateral documentation in favor of CIBC. The CIBC Loan originally had a five-year term maturing on February 20, 2025, which included 24 months of interest only payments followed by 36 months of equal payments of principal and interest. The interest only period can be extended to 36 months if the Company achieves three-month trailing revenue of at least \$20.0 million as of February 20, 2022. The CIBC Loan bears interest at a floating rate equal to 1.0% above the Wall Street Journal Prime Rate at any time. The Tranche C loan will bear interest at a floating rate



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equal to 1.5% above the Wall Street Journal Prime Rate at any time. The CIBC Loan is collateralized by substantially all of the Company's assets, including cash and cash equivalents, accounts receivable, intellectual property and equipment. The Company may prepay the loan, subject to certain requirements. The CIBC Agreement includes customary restrictive covenants, financial covenants, events of default and other customary terms and conditions.

In April 2020, the Company entered into a First Amendment to CIBC Agreement that changed the maturity date to March 15, 2022, which would be automatically extended to February 20, 2025 if the maturity of all outstanding convertible notes was extended to a date no earlier than May 21, 2025 or all convertible notes converted into convertible preferred stock of the Company. An amendment fee of \$0.2 million was paid. The Tranche B drawing is conditioned to achieving a trailing six-month revenue of at least \$15.0 million as of the date of any Tranche B borrowing. On the date of drawing Tranche B Loan or Tranche C Loan, the Company will pay a structuring fee in an amount equal to 1.0% of the amount of Tranche B Loan or Tranche C Loan. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In December 2020, to address certain post-close covenants for which the Company was not in compliance, the Company entered into a Second Amendment to the CIBC Agreement that extended the compliance date for certain post-close covenants to June 30, 2021.

In March 2021, the Company entered into an Amended and Restated Agreement which extended the maturity date from March 15, 2022 to February 20, 2025, and modified certain financial covenants. Per the amended terms, 36 equal payments of principal plus accrued interest will be due beginning March 31, 2022. The beginning of principal repayment can be extended to March 31, 2023 if the Company achieves three-month trailing revenue of at least \$20.0 million as of February 20, 2022. In connection with the an amended and restated agreement, the Company paid fees to CIBC of less than \$0.1 million which were recorded as a discount on the CIBC Loan and are being accreted over the life of the term loan using the effective interest method. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In June 2021, the Company entered into a First Amendment to the Amended and Restated Loan and Security agreement with CIBC that extended the compliance of certain post-close covenants to March 31, 2022.

In October 2021, the Company entered into a Second Amendment to the Amended and Restated Loan and Security Agreement with CIBC, which extended the interest only period of the loan from 24 months to 36 months. Under the amended terms, principal repayment will begin in February 2023. There was no change to the loan interest rate or maturity date.

As of December 31, 2021, the CIBC Loan had an annual effective interest rate of 4.71% per year.

The financial covenants in the CIBC Agreement require that, when the cash and cash equivalents of the Company is less than \$100.0 million, the Company have revenue for the trailing three-month period ending on the last day of each fiscal quarter of not less than 80.0% of the revenue for the trailing three-month period, as set forth in the annual projections delivered to the CIBC. Further, the Company is required to maintain unrestricted cash in an aggregate amount equal to or greater than the Adjusted EBITDA loss as defined in the CIBC Agreement for the four-month period ending on any date of determination. As of December 31, 2021, the Company was in compliance with all covenants contained in CIBC Agreement.

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The CIBC Loan consists of the following (in thousands):

	December 31, 2021	December 31, 2020
Term loan	\$ 17,000	\$ 17,000
Less: debt issuance costs	(131)	(196)
Term loan	<u>\$ 16,869</u>	<u>\$ 16,804</u>

The Company paid \$0.4 million fees to the lender and third parties, which is reflected as a discount on the CIBC Loan and is being accreted over the life of the term loan using the effective interest method.

During the year ended December 31, 2021 and December 31, 2020, the Company recorded interest expense related to debt discount and debt issuance costs of CIBC Loan of \$0.1 million and \$0.1 million, respectively.

Interest expense on the CIBC Loan amounted to \$0.8 million and \$0.7 million during the year ended December 31, 2021 and December 31, 2020, respectively.

### **Credit Agreement**

In April 2020, Pulmonx International Sàrl, a wholly owned subsidiary of the Company, entered into a COVID-19 Credit Agreement with UBS Switzerland AG to receive up to 0.5 million Swiss Francs (\$0.5 million U.S. dollar equivalent) under Swiss Federal Government program to mitigate the economic impact of the spread of the coronavirus. In May 2020, Pulmonx International Sàrl received 0.5 million Swiss Francs (\$0.5 million U.S. dollar equivalent) under the COVID-19 Credit Agreement. The COVID-19 Credit Agreement bears no interest and will be repaid in twelve equal installments, paid semi-annually, beginning in March of 2022.

### **2020 Notes**

In April 2020, the Company entered into a Note Purchase Agreement and Convertible Promissory Notes (collectively the “2020 Notes Agreement”) with certain investors (the “Lenders”) to issue convertible promissory notes (the “2020 Notes”) for a maximum aggregate amount of \$66.0 million. In April 2020, the Company received \$33.0 million in gross proceeds from issuance of the 2020 Notes. Upon meeting customary closing conditions, the Company can draw up to an additional \$33.0 million, provided that any such draw be for no less than \$5.0 million on or prior to April 17, 2022. All unpaid interest and principal will be due and payable upon request of the majority of Lenders (“Majority Holders”) on or after the earlier of April 17, 2022 or an event of default. The 2020 Notes accrue interest at a rate equal to 2.0% above the Wall Street Journal Prime Rate. The Company may prepay the 2020 Notes prior to April 17, 2022 only with the consent of the Majority Holders.

The 2020 Notes included embedded derivatives that were required to be bifurcated from the 2020 Notes and accounted for separately as a single, compound embedded derivative instrument under ASC 815, *Derivatives* (“2020 Notes derivative liability”). The Company determined that a share settled redemption in the case of a financing or an IPO as described in the 2020 Notes represented an embedded derivative that was not clearly and closely related to the debt host and had accounted for these settlement alternatives as separate embedded derivative liability. The fair value of the 2020 derivative liability of \$3.9 million was recorded on the issuance date of the 2020 Notes resulting in a debt discount, which was reported as a direct deduction from the face amount of the 2020 Notes. The 2020 derivative liability was remeasured to its fair value at the end of each reporting period and any change in fair value is recognized in other income (expense), net in the statements of operations and comprehensive loss (Note 4). The change in fair value of \$3.9 million during the year ended December 31, 2020 was recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

Upon the closing of the IPO in October 2020, the \$33.0 million aggregate outstanding principal amount and \$0.8 million accrued interest of the 2020 Notes converted into 2,561,484 shares of common stock pursuant to the

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Qualified IPO conversion at the \$13.20 per share fixed price. The Company determined that the 2020 Notes derivative had no value upon the closing of the IPO, because value of the notes with and without such derivative was the same.

The Company incurred debt issuance costs of \$0.1 million in connection with the 2020 Notes Agreement, which were reported on the balance sheet as a direct deduction from the face amount of the 2020 Notes.

During the year ended December 31, 2020, the Company recorded interest expense of \$1.6 million on the 2020 Notes, consisting of \$0.8 million of contractual interest expense and \$0.8 million amortization of debt discount and debt issuance costs. Before the conversion upon the IPO, the 2020 Notes had an annual effective interest rate of 12.33% per year.

At December 31, 2021, the Company retained the ability to draw up to an additional \$33.0 million under the 2020 Notes Agreement until the maturity date in April 2022. The Company's obligations with respect to the 2020 Notes are unsecured and subordinated to its obligations with respect to the CIBC Loan. The 2020 Notes have customary events of default.

#### **Contractual Maturities of Financing Obligations**

As of December 31, 2021, the aggregate future payments under the CIBC Loan and Credit Agreement (including interest payments) are as follows (in thousands):

2022	\$	814
2023		7,783
2024		8,847
2025		1,514
2026		91
2027		91
<b>Total</b>	<b>\$</b>	<b>19,140</b>
Less: unamortized debt discount		(131)
Less: interest		(1,594)
Term loan and credit agreement	<b>\$</b>	<b>17,415</b>

#### **7. Revenue Recognition**

The Company's contract liabilities consist of deferred revenue for remaining performance obligations by the Company to the customer after delivery, which was \$0.2 million as of December 31, 2021, which is expected to be recognized as revenue in 2022. The deferred revenue as of December 31, 2020 was \$0.1 million, which was recognized as revenue during the year ended December 31, 2021.

The Company disaggregates its revenue by major geographic region, which has been disclosed in Note 12, "Segment Information".

#### **8. Leases, Lease Commitments and Contingencies**

The Company has a lease for its headquarters location in Redwood City, California. In October 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 is \$0.1 million and is subject to an annual increase of 3.5%. The Company is responsible for its share of real estate taxes, common area maintenance and management fees. The Company is eligible to receive a tenant improvement allowance of \$0.2 million on commencement of the renewal term in August 2020.

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During 2013, the Company entered into a five-year lease for office facilities in Switzerland. The Company had an option to extend the lease through January 2022, which was not exercised by the Company. Per the lease terms, in the event the option to extend is not exercised, the lease remains in force and can be terminated with 12-months' notice.

In April 2020, the Company executed a sublease for another office facility in Redwood City, California for a three-year term commencing on June 1, 2020. The lease agreement provides for early termination if the Company or Sublandlord elects to terminate the lease by providing the other party at least 180 days prior written notice. The early termination may only occur on or after the expiration of the 18th full calendar month of the sublease term. The monthly base rent during the term is less than \$0.1 million and is subject to an annual increase of 3.5%. The Company is responsible for its share of real estate taxes, common area maintenance and management fees.

In September 2020, the Company amended a sublease agreement entered into in April 2020, to include additional facility space in Redwood City, California for a four-year term. The amendment was accounted as a separate sublease agreement. The sublease agreement contained a rent-free period through February 14, 2021, after which rent is approximately \$0.1 million per month and is subject to an annual increase of 3.5%. The Company is responsible for its share of real estate taxes, common area maintenance and management fees. The Company is eligible to receive a tenant improvement allowance of \$0.7 million to fund facility enhancements. The sublease agreement can be extended for an additional twelve-month period, at the Company's option. For accounting purposes, the lease term is 4 years as it is not reasonably certain that the Company will exercise the renewal option. The amendment also changed the lease term entered into in April 2020, which was extended until May 31, 2024, but left the early termination clause unchanged. In September 2021, the Company became reasonably certain that the early termination clause would not be exercised as capital expenditures on the facility build-out created sufficient disincentive to terminate the lease early. The lease term was reevaluated and extended from November 30, 2021 to May 31, 2024.

The Company has leases on four vehicles with an average lease term of 3 years.

Operating lease cost consists of the following (in thousands):

	Years Ended December 31,	
	2021	2020
Operating lease cost	\$ 2,878	\$ 2,078
Short-term lease cost	19	12
Variable lease cost	598	337
<b>Total lease cost</b>	<b>\$ 3,495</b>	<b>\$ 2,427</b>

The following table summarizes a maturity analysis of the Company's lease liabilities showing the aggregate lease payments as of December 31, 2021 (in thousands):

2022	\$ 2,666
2023	3,407
2024	2,884
2025	1,008
<b>Total minimum lease payments</b>	<b>9,965</b>
Less: Amount of lease payments representing interest	920
<b>Present value of future minimum lease payments</b>	<b>\$ 9,045</b>
Less: Current lease liabilities	2,201
<b>Long-term lease liabilities</b>	<b>\$ 6,844</b>

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The following table summarizes additional information related to the Company's operating leases (in thousands, except weighted average data):

	December 31,	
	2021	2020
Right of use asset	\$ 8,075	\$ 8,976
Weighted average remaining lease term (years)	3.17	4.13
Weighted average discount rate (percent)	6.0	6.1

The following table summarizes other supplemental information related to the Company's operating leases (in thousands):

	Years Ended December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities included in cash flows used in operating activities	\$ 2,805	\$ 1,494
Right-of-use assets obtained in exchange for lease liabilities	\$ 1,460	\$ 3,935

### **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 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.

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**9. Income Taxes**

Income before the provision for income taxes consists of the following (in thousands):

	Years Ended December 31,	
	2021	2020
Domestic	\$ (49,176)	\$ (28,029)
Foreign	858	(3,989)
<b>Total loss before provision for taxes</b>	<b>\$ (48,318)</b>	<b>\$ (32,018)</b>

The components of income tax expense are as follows (in thousands):

	Years Ended December 31,	
	2021	2020
<b>Current:</b>		
Federal	\$ —	\$ —
State	46	9
Foreign	321	185
<b>Total current expense</b>	<b>367</b>	<b>194</b>
<b>Deferred:</b>		
Federal	(18)	6
State	(1)	6
Foreign	(5)	7
<b>Total deferred expense</b>	<b>(24)</b>	<b>19</b>
<b>Total income tax expense</b>	<b>\$ 343</b>	<b>\$ 213</b>

The reconciliation between the federal statutory rate and the Company's effective tax rate is summarized below:

	Years Ended December 31,	
	2021	2020
Federal statutory rate	21.0 %	21.0 %
State taxes, net of federal benefit	(0.1)%	10.2 %
Foreign earnings at different rates	(0.1)%	(3.9)%
Tax credits	0.4 %	0.6 %
Permanent differences	4.4 %	(0.3)%
Prior year true-up	0.0 %	0.3 %
Change in valuation allowance	(26.3)%	(40.5)%
Entity restructuring	0.0 %	11.9 %
<b>Effective tax rate</b>	<b>(0.7)%</b>	<b>(0.7)%</b>

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

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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):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 43,804	\$ 30,400
Tax credit carryforwards	5,579	5,240
Accruals and Reserves	1,638	939
Intangible Assets	4,952	5,287
Other	1,057	449
Gross deferred tax assets	57,030	42,315
Less: valuation allowance	(56,551)	(41,922)
Deferred tax assets	479	393
Deferred tax liabilities:		
Depreciation	(43)	(27)
Goodwill	(473)	(428)
Net deferred tax liabilities	\$ (37)	\$ (62)

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 \$56.6 million as of December 31, 2021. The valuation allowance increased by \$14.6 million and \$13.0 million for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, the Company had total net operating loss carryforwards for federal income tax purposes of approximately \$181.5 million, of which \$71.9 million was generated before 2018. If not utilized, these pre-2018 net federal operating loss carryforwards will begin to expire at the end of the year. The Company also had a state net operating loss carryforward of approximately \$325.5 million which will expire beginning in the year 2022.

For tax years in January 1, 2018 onwards, any federal net operating losses generated will be allowable for carry forward indefinitely, as opposed to the original expiration of 20 years. As of December 31, 2021, the Company had \$109.7 million of post-2017 federal net operating losses that can be carryforward indefinitely.

The Company also had federal and state research and development ("R&D") tax credit carryforwards of approximately \$3.0 million and \$4.5 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.

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. The Company completed another section 382 study for the year ended December 31, 2020 for which the Company had a change in ownership. No additional NOLs or credits will expire unused due to the 2020 annual limitation. Management determined that there was no ownership change in 2021.

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

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consolidated financial statements. As of December 31, 2021, the Company had unrecognized tax benefits of approximately \$8.5 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 January 1, 2020	\$	989
Additions for tax positions related to current year		7,259
Balance at December 31, 2020	\$	8,248
Additions for tax positions related to prior year		173
Additions for tax positions related to current year		68
Balance at December 31, 2021	\$	8,489

It is the Company's policy to include penalties and interest expense related to income taxes as part of the provision for income taxes.

The Company's major tax jurisdictions are the United States and California, Switzerland and Neuchâtel. 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.

## 10. Stockholders' Equity

### *Common Stock*

As of December 31, 2021 and December 31, 2020, the Company's certificate of incorporation authorized the Company to issue up to 200,000,000 and 200,000,000 shares of common stock, respectively. 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:

	December 31,	
	2021	2020
Common stock options issued and outstanding	2,145,131	2,923,403
Common stock restricted stock units issued and outstanding	442,428	—
Common stock available for future grants	3,751,115	3,233,794
Common stock available for ESPP	932,458	720,000
Total	7,271,132	6,877,197

### *Stock Option Plan*

As of December 31, 2021, the Company reserved 11,269,901 shares of its common stock under its 2000 Stock Plan (the "2000 Stock Plan"), the 2010 Stock Plan (the "2010 Stock Plan"), the 2020 Stock Plan (the "2020 Stock Plan"), and the 2020 Equity Incentive Plan (the "2020 Equity Incentive Plan" and, together with the 2000 Stock Plan, the



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2010 Stock Plan and the 2020 Stock Plan, the “Stock Plans”). 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, 2021 and December 31, 2020, 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 non-employee 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 Stock Plans is set forth below:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balance, December 31, 2019	3,279,324	\$ 1.66
Options granted	1,466,071	7.73
Options exercised	(1,745,040)	1.55
Options canceled	(76,952)	3.55
Balance, December 31, 2020	2,923,403	\$ 4.72
Options granted	421,200	43.79
Options exercised	(1,065,567)	1.77
Options canceled	(133,905)	11.44
Balance, December 31, 2021	2,145,131	\$ 13.44

The aggregate intrinsic value of options exercised during the years ended December 31, 2021, December 31, 2020 was \$43.8 million, \$2.0 million, respectively.

The weighted average exercise price and aggregate intrinsic value of options outstanding at December 31, 2021 was \$13.44 per share and \$45.3 million, respectively. The weighted average exercise price and aggregate intrinsic value of options outstanding at December 31, 2020 was \$4.72 per share and \$188.0 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, 2021 and December 31, 2020.

	December 31, 2021		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Life (in Years)
Options vested	751,752	\$ 7.91	7.13
Options vested and expected to vest	2,145,131	\$ 13.44	8.15

Total intrinsic value of options vested as of December 31, 2021 and December 31, 2020 was \$18.9 million and \$81.7 million, respectively.

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**Early Exercise of Stock Options**

Under the terms of the individual option grants, options granted from the 2000 Stock Plan, the 2010 Stock Plan and the 2020 Stock Plan 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, 2021 and 2020, the Company repurchased 12,945 and 10,000 shares of common stock for less than \$0.1 million and less than \$0.1 million, respectively. As of December 31, 2021 and December 31, 2020, 223,195 and 355,677 shares were subject to repurchase, with an aggregate exercise price of \$0.4 million and \$0.6 million, respectively, and were recorded in other current liabilities.

**Restricted Stock Units**

Activity with respect to restricted stock units was as follows:

	Number of Shares Underlying Outstanding Restricted Stock	Weighted Average Grant Date Fair Value
Unvested, January 1, 2021	—	\$ —
Granted	503,110	42.49
Vested	(40,908)	43.40
Canceled	(19,774)	43.60
Unvested, December 31, 2021	442,428	\$ 42.36

The aggregate intrinsic value of restricted stock units outstanding as of December 31, 2021 was \$14.2 million.

**Stock-Based Compensation for Employees and Non-Employees**

The weighted average grant-date fair value of the stock options granted during the years ended December 31, 2021, December 31, 2020 was \$18.81 and \$3.78 per share, respectively.

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:

	Years Ended December 31,	
	2021	2020
Weighted average expected term (in years)	5.0 - 6.3	5.0 - 6.1
Volatility	44.0% - 44.5%	40.0% - 44.7%
Risk-free interest rate	0.6% - 1.0%	0.2% - 1.7%
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

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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, 2021 and December 31, 2020 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**

Prior to the IPO 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. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.

**2020 Employee Share Purchase Plan**

In September 2020, the Company adopted the ESPP, which became effective on the business day prior to the effectiveness of the registration statement relating to the IPO. A total of 720,000 shares of common stock were initially reserved for issuance under the ESPP. The ESPP permits eligible employees to acquire shares of the Company's common stock through periodic payroll deductions of up to 15% of base compensation. No employee may purchase more than 2,500 shares during an offering period. In addition, no employee may purchase more than \$25,000 worth of stock, determined by the fair market value of the shares at the time such option is granted, in one calendar year. At the end of each purchase period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last trading day of the offering period. The first offering period started on September 30, 2020 and ended on May 24, 2021, and the second offering period started on June 1, 2021 and ended on August 15, 2021. Beginning August 16, 2021, the ESPP provides for six-month offering periods, with the purchase date being the last date of the offering period.

The Company issued 144,479 shares under the ESPP for the year ended December 31, 2021. As of December 31, 2021, there are 932,458 shares authorized for future purchase under the ESPP. In January 2022, the number of shares of common stock available for issuance under the ESPP was increased by 369,317 shares as a result of the automatic increase provision in the ESPP.

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Compensation expense is calculated using the fair value of the employees' purchase rights under the Black-Scholes model.

	Year Ended December 31, 2021	Year Ended December 31, 2020
Weighted average expected term (in years)	0.5	0.6
Volatility	36.1% - 42%	67.7% - 68.2%
Risk-free interest rate	0.1%	0.1%
Dividend yield	—	—

**Total Stock-Based Compensation**

Stock-based compensation expense is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Cost of goods sold	\$ 587	\$ 39
Research and development	1,278	398
Selling, general and administrative	8,665	2,760
Total	<u>\$ 10,530</u>	<u>\$ 3,197</u>

The above stock-based compensation expense related to the following equity-based awards:

	Years Ended December 31,	
	2021	2020
Stock options and restricted stock units	\$ 7,959	\$ 2,055
ESPP	2,571	1,142
Total	<u>\$ 10,530</u>	<u>\$ 3,197</u>

Stock-based compensation of \$1.0 million and \$0.3 million was capitalized into inventory for the years ended December 31, 2021 and 2020, respectively. Capitalized stock-based compensation is recognized as cost of sales when the related product is sold.

As of December 31, 2021, there was \$33.7 million of unrecognized compensation costs related to non-vested common stock options and restricted stock units, expected to be recognized over a weighted-average period of 3.15 years, respectively. The total grant date fair value of shares vested during the years ended December 31, 2021 and December 31, 2020 was \$8.3 million and \$1.9 million, respectively.

As of December 31, 2021, the Company had unrecognized employee stock-based compensation relating to ESPP awards of approximately \$0.1 million, which is expected to be recognized over a weighted-average period of 0.1 years.

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

### 11. 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):

	Years Ended December 31,	
	2021	2020
<b>Numerator</b>		
Net loss attributable to common stockholders	\$ (48,661)	\$ (32,231)
<b>Denominator</b>		
Weighted-average common stock outstanding	36,406,507	10,341,809
Less: weighted-average common shares subject to repurchase	(277,098)	(156,968)
Weighted-average common shares used to compute basic and diluted net loss per share	36,129,409	10,184,841
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.35)	\$ (3.16)

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:

	Years Ended December 31,	
	2021	2020
Options to purchase common stock	2,145,131	2,923,403
Unvested restricted stock units	442,428	—
Unvested early exercised common stock options	223,195	355,677
Shares committed under ESPP	27,327	47,174

### 12. 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):

	Year Ended December 31,	
	2021	2020
United States	\$ 24,991	\$ 16,189
Europe, Middle-East and Africa ("EMEA")	19,883	13,808
Asia Pacific	3,414	2,687
Other International	128	49
Total	\$ 48,416	\$ 32,733

**Pulmonx Corporation**  
**Notes to Consolidated Financial Statements**

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Revenue from Germany represented 12%, and 17% of total revenue for the years ended December 31, 2021 and 2020, respectively.

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):

	December 31,	
	2021	2020
United States	\$ 4,767	\$ 1,437
Europe, Middle-East and Africa	42	29
Asia Pacific	5	8
Total	<u>\$ 4,814</u>	<u>\$ 1,474</u>

### 13. 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.

### 14. Related Parties

From 2013 to 2020, the Company 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 years ended December 31, 2020 was less than \$0.1 million.

### 15. Subsequent Events

Subsequent to December 31, 2021, the Company granted 701,250 restricted stock units and options to purchase 655,200 shares of common stock to employees, subject to service-based vesting conditions. The options have an exercise price equal to the closing price of our common stock on March 1, 2022.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

### ITEM 9A. CONTROLS AND PROCEDURES

#### **Evaluation of our Disclosure Controls and Procedures**

Disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, are controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that, due to the material weakness described below, our disclosure controls and procedures were not effective as of December 31, 2021.

#### *Inherent Limitations on Effectiveness of Controls*

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. Further, our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with generally accepted accounting principles in the United States ("GAAP"). Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of our consolidated financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our control system will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

#### **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Under the supervision of our management, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021 based on the criteria set forth in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway

Commission. Based on that assessment, our management has concluded that, due to the material weakness described below, our internal control over financial reporting was not effective as of December 31, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by our independent registered public accounting firm, BDO USA, LLP, as stated in their report which is included herein.

*Material Weakness*

We determined a material weakness existed relating to ineffective information technology general controls in the areas of user access and segregation of duties related to certain information technology systems that support our financial reporting process specifically related to expenditures. Although these control weaknesses did not result in any material misstatement of our consolidated financial statements for the periods presented, they could lead to a material misstatement of account balances or disclosures. Accordingly, our management has concluded that these control weaknesses constitute a material weakness.

Our management, under the oversight of our Audit Committee and in consultation with outside advisors, has begun evaluating and implementing measures designed to ensure that the control deficiencies contributing to the material weakness are remediated. These remediation measures include, but are not limited to: (i) evaluating and implementing enhanced process controls around user access management; and (ii) expanding the management and governance over user access and system controls.

We believe the above actions will be effective in remediating the material weakness described above and we will continue to devote time and attention to these remedial efforts. However, as we continue to evaluate and take actions to improve our internal control over financial reporting, we may take additional actions to address control deficiencies or modify certain of the remediation measures described above. Our remediation efforts will not be considered complete until the applicable controls operate for a sufficient period of time and our management has concluded, through testing, that these controls are operating effectively.

Notwithstanding the material weakness described above, our management has concluded that the consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with GAAP.

**Changes in Internal Control over Financial Reporting**

Other than as described above, there has been no change in our internal control over financial reporting during the quarter ended December 31, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



## Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors  
Pulmonx Corporation  
Redwood City, California

### Opinion on Internal Control over Financial Reporting

We have audited Pulmonx Corporation's (the "Company's") internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of income and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows for the years then ended, and the related notes and our report dated March 1, 2022 expressed an unqualified opinion thereon.

### Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness regarding ineffective controls around user access and segregation of duties involving certain information technology systems related to expenditures has been identified and described in management's assessment. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2021 financial statements, and this report does not affect our report dated March 1, 2022 on those financial statements.

### Definition and Limitations of Internal Control over Financial Reporting

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

with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ BDO USA, LLP

San Francisco, California

March 1, 2022

**ITEM 9B. OTHER INFORMATION**

None.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information regarding our directors and executive officers set forth under the headings “Proposal No.1—Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” and “Information Regarding Executive Officers” of the 2022 Proxy Statement is incorporated herein by reference.

Information regarding our Audit Committee, including the members of our Audit Committee, set forth under the heading “Information Regarding the Board of Directors and Corporate Governance—Audit Committee” of the 2022 Proxy Statement is incorporated herein by reference.

Information regarding the procedures by which our shareholders may recommend nominees to our Board of Directors set forth under the heading “Information Regarding the Board of Directors and Corporate Governance—Nominating and Corporate Governance Committee” of the 2022 Proxy Statement is incorporated herein by reference.

Information regarding compliance with Section 16(a) of the Exchange Act, if any, set forth under the heading “Delinquent Section 16(a) Reports” of the 2022 Proxy Statement is incorporated herein by reference.

Information regarding our Code of Business Conduct and Ethics set forth under the heading “Information Regarding the Board of Directors and Corporate Governance—Code of Business Conduct and Ethics” of the 2022 Proxy Statement is incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

Information regarding executive compensation and director compensation set forth under the headings “Executive Compensation” and “Director Compensation,” respectively, of the 2022 Proxy Statement is incorporated herein by reference.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information contained in the sections captioned “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” of the 2022 Proxy Statement is incorporated herein by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information contained in the section captioned “Transactions with Related Persons and Indemnification” of the 2022 Proxy Statement is incorporated herein by reference.

Information regarding director independence set forth under the heading “Information Regarding the Board of Directors and Corporate Governance” of the 2022 Proxy Statement is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information regarding our independent auditor fees and services in the section captioned “Proposal No. 2—Ratification of Selection of Independent Registered Public Accounting Firm—Principal Accounting Fees and Services” of the 2022 Proxy Statement is incorporated herein by reference.

Our Audit Committee’s policy on pre-approval of audit and permissible non-audit services of our independent auditor in the section captioned “Proposal No. 2—Ratification of Selection of Independent Registered Public Accounting Firm—Pre-Approval Policies and Procedures” of the 2022 Proxy Statement is incorporated herein by reference.

**PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

**(1) FINANCIAL STATEMENTS**

Our consolidated financial statements are listed in the “Index to the Financial Statements” under Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

**(2) FINANCIAL STATEMENT SCHEDULES**

All schedules to the financial statements are omitted because they are not applicable, not material or the required information is shown in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

**(3) EXHIBITS**

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this Annual Report on Form 10-K, in each case as indicated therein.

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed Herewith</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Pulmonx Corporation.</a>	8-K	001-39562	3.1	October 5, 2020	
3.2	<a href="#">Amended and Restated Bylaws of Pulmonx Corporation.</a>	S-1/A	333-248635	3.4	September 24, 2020	
4.1	<a href="#">Form of common stock certificate of Pulmonx Corporation.</a>	S-1/A	333-248635	4.1	September 24, 2020	
4.2	<a href="#">Amended and Restated Investors’ Rights Agreement by and among Pulmonx Corporation and certain of its stockholders, dated April 16, 2019.</a>	S-1/A	333-248635	4.2	September 24, 2020	
4.3	<a href="#">Description of common stock of Pulmonx Corporation.</a>	10-K	001-39562	4.3	March 15, 2021	
10.1+	<a href="#">Amended and Restated 2010 Stock Plan.</a>	S-8	333-249187	99.1	October 1, 2020	
10.2+	<a href="#">Forms of Notice of Stock Option Grant, Option Agreement, and Exercise Notice under Amended and Restated 2010 Stock Plan.</a>	S-8	333-249187	99.2	October 1, 2020	
10.3+	<a href="#">Amended and Restated 2020 Stock Plan.</a>	S-8	333-249187	99.3	October 1, 2020	
10.4+	<a href="#">Forms of Notice of Stock Option Grant, Option Agreement, and Exercise Notice under Amended and Restated 2020 Stock Plan.</a>	S-8	333-249187	99.4	October 1, 2020	

10.5+	<a href="#">2020 Equity Incentive Plan.</a>	S-8	333-249187	99.5	October 1, 2020
10.6+	<a href="#">Forms of Option Agreement and Notice of Stock Option Grant under 2020 Equity Incentive Plan.</a>	S-8	333-249187	99.6	October 1, 2020
10.7+	<a href="#">Form of Restricted Stock Unit Award Agreement under 2020 Equity Incentive Plan.</a>	S-8	333-249187	99.7	October 1, 2020
10.8+	<a href="#">2020 Employee Stock Purchase Plan.</a>	S-8	333-249187	99.8	October 1, 2020
10.9	<a href="#">Form of Indemnification Agreement by and between Pulmonx Corporation and each of its directors and executive officers.</a>	S-1/A	333-248635	10.9	September 24, 2020
10.10+	<a href="#">Executive Employment Agreement, by and between Pulmonx Corporation and Glendon E. French, dated December 10, 2014.</a>	S-1/A	333-248635	10.10	September 24, 2020
10.11+	<a href="#">Offer Letter Agreement, by and between Pulmonx Corporation and Geoffrey Beran Rose, dated December 11, 2014.</a>	S-1/A	333-248635	10.11	September 24, 2020
10.12+	<a href="#">Offer Letter Agreement, by and between Pulmonx Corporation and Derrick Sung, Ph.D., dated March 12, 2019.</a>	S-1/A	333-248635	10.12	September 24, 2020
10.13+	<a href="#">Offer Letter Agreement, by and between Pulmonx Corporation and David Lehman, dated September 15, 2020</a>	10-K	001-39562	10.13	March 15, 2021
10.14+	<a href="#">Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated October 1, 2013.</a>	S-1/A	333-248635	10.13	September 24, 2020
10.15+	<a href="#">Amendment to Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated March 1, 2014.</a>	S-1/A	333-248635	10.14	September 24, 2020
10.16+	<a href="#">Second Amendment to Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated July 14, 2014.</a>	S-1/A	333-248635	10.15	September 24, 2020
10.17+	<a href="#">Third Amendment to Consulting Agreement, by and between PulmonX International Sàrl and Orsco Life Sciences AG, dated April 27, 2015.</a>	S-1/A	333-248635	10.16	September 24, 2020
10.18+	<a href="#">Appointment Letter, by and between PulmonX International Sàrl and Oern R. Stuge, dated December 18, 2013.</a>	S-1/A	333-248635	10.17	September 24, 2020
10.19	<a href="#">Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated September 4, 2009.</a>	S-1/A	333-248635	10.18	September 24, 2020
10.20	<a href="#">First Amendment to Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated October 3, 2014.</a>	S-1/A	333-248635	10.19	September 24, 2020



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10.21	<a href="#">Second Amendment to Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated November 7, 2019.</a>	S-1/A	333-248635	10.20	September 24, 2020	
10.22	<a href="#">Sublease, by and between Pulmonx Corporation and Genomic Health, Inc., dated April 8, 2020.</a>	S-1/A	333-248635	10.21	September 24, 2020	
10.23	<a href="#">First Amendment to Sublease Agreement, by and between Pulmonx Corporation and Genomic Health, Inc., dated September 10, 2020.</a>	S-1/A	333-248635	10.22	September 24, 2020	
10.24	<a href="#">Intellectual Property Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank of Commerce, dated February 20, 2020.</a>	S-1/A	333-248635	10.25	September 24, 2020	
10.25	<a href="#">Note Purchase Agreement and Form of 2020 Note, by and between Pulmonx Corporation and the purchasers of the 2020 Notes, dated April 17, 2020.</a>	S-1/A	333-248635	10.26	September 24, 2020	
10.26+	<a href="#">Pulmonx Corporation Severance and Change in Control Plan and related participation agreement.</a>	S-1/A	333-248635	10.27	September 28, 2020	
10.27	<a href="#">Second Amendment and Waiver to Loan and Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank of Commerce, dated December 28, 2020.</a>	10-Q	001-39562	10.1	May 12, 2021	
10.28	<a href="#">Amended and Restated Loan and Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank Commerce, dated March 29, 2021.</a>	10-Q	001-39562	10.2	May 12, 2021	
10.29+	<a href="#">Amended and Restated Non-Employee Director Compensation Policy.</a>	10-Q	001-39562	10.3	May 12, 2021	
10.30	<a href="#">First Amendment to Amended and Restated Loan and Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank of Commerce, dated June 17, 2021.</a>	10-Q	001-39562	10.1	August 10, 2021	
10.31	<a href="#">Second Amendment to Amended and Restated Loan and Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank of Commerce, dated October 21, 2021.</a>	10-Q	001-39562	10.1	November 9, 2021	
21.1	<a href="#">List of Subsidiaries of Registrant.</a>					X
23.1	<a href="#">Consent of BDO USA, LLP, independent registered public accounting firm.</a>					X
24.1	<a href="#">Power of Attorney (included on signature page hereto).</a>					X

31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X
32.1*	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	
32.2*	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X

+ Indicates management contract or compensatory plan

\* The certifications attached as Exhibits 32.1 and 32.2 accompanying this Annual Report on Form 10-K are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Company under the Securities Act or the Exchange Act whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

## ITEM 16. FORM 10-K SUMMARY

None.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, 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 1st day of March, 2022.

**PULMONX CORPORATION**

By: /s/Glendon E. French  
 Glendon E. French  
*President, Chief Executive Officer and Director*

By: /s/Derrick Sung  
 Derrick Sung, Ph.D.  
*Chief Financial Officer*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Glendon E. French and Derrick Sung, jointly and severally, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/Glendon E. French</u> Glendon E. French	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2022
<u>/s/Derrick Sung, Ph.D.</u> Derrick Sung, Ph.D.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2022
<u>/s/Thomas W. Burns</u> Thomas W. Burns	Director	March 1, 2022
<u>/s/Richard Ferrari</u> Richard Ferrari	Director	March 1, 2022
<u>/s/Daniel P. Florin</u> Daniel P. Florin	Director	March 1, 2022
<u>/s/Georgia Garinois-Melenikiotou</u> Georgia Garinois-Melenikiotou	Director	March 1, 2022
<u>/s/Alissa Hsu Lynch</u> Alissa Hsu Lynch	Director	March 1, 2022
<u>/s/Dana G. Mead, Jr.</u> Dana G. Mead, Jr.	Director	March 1, 2022
<u>/s/Tiffany Sullivan</u> Tiffany Sullivan	Director	March 1, 2022

**Subsidiaries of Pulmonx Corporation**

<b>Name of Subsidiary</b>	<b>Jurisdiction of Organization</b>
Pulmonx Australia Pty Ltd	Australia
Pulmonx France SAS	France
Pulmonx Global B.V.	The Netherlands
Pulmonx GmbH	Germany
Pulmonx Hong Kong Limited	Hong Kong
PulmonX International Sàrl	Switzerland
Pulmonx Italy Srl	Italy
Pulmonx UK Limited	United Kingdom

Consent of Independent Registered Public Accounting Firm

Pulmonx Corporation  
Redwood City, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-249187 and 333-256140) of Pulmonx Corporation of our reports dated March 1, 2022, relating to the consolidated financial statements, and the effectiveness of Pulmonx Corporation's internal controls over financial reporting, which appear in this Form 10-K. Our report on the effectiveness of internal control over financial reporting expresses an adverse opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2021.

/s/ BDO USA, LLP

San Francisco, California

March 1, 2022

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Glendon E. French, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulmonx Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

By: \_\_\_\_\_ /s/ Glendon E. French

Glendon E. French  
President, Chief Executive Officer and Director

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Derrick Sung, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulmonx Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

By:

/s/ Derrick Sung

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Derrick Sung, Ph.D.  
Chief Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Pulmonx Corporation (the "Company") on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 1, 2022

By:

/s/ Glendon E. French

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Glendon E. French

President, Chief Executive Officer and Director



**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Pulmonx Corporation (the "Company") on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 1, 2022

By:

/s/ Derrick Sung

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Derrick Sung, Ph.D.  
Chief Financial Officer