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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, 2023

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	**77-0424412**
(State or other jurisdiction of incorporation or organization)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

As of February 19, 2024, there were 38,537,356 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, 2023, was approximately $478.5 million. 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 2024 annual meeting of stockholders (the "2024 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2024 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 chronic obstructive pulmonary disease ("COPD") and emphysema;
- our expected future growth, including growth in international sales;
- our expected future growth of our sales and marketing organization;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- the rate and degree of market acceptance of our products;
- coverage and reimbursement for procedures performed using our products;
- the performance of third parties in connection with the development of our products, including third-party suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval, certification 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;
- 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

- our expectations regarding the impact of any public health crises, such as a resurgence of COVID-19 infections, on our business, financial condition and results of operations.

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;

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

- If we fail to receive access to hospital facilities our sales may decrease;

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

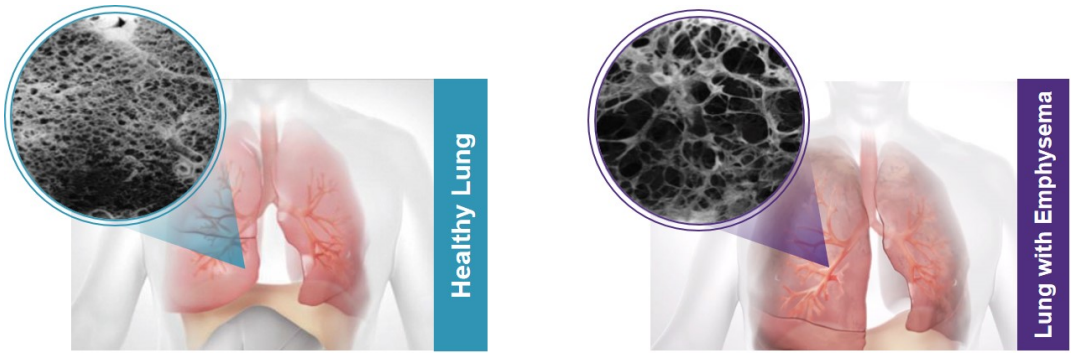
PART I

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. Patients with severe emphysema generally experience a worse quality of life than patients with lung cancer, and we believe there is both an urgent clinical need and a strong market opportunity for a solution that is safe, effective and minimally invasive.

In June 2018, we received pre-market approval ("PMA") by the U.S. Food and Drug Administration ("FDA"). 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.



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 long-term survival benefits.

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 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 96% of our revenue generated in markets where we sell directly for the year ended December 31, 2023.

We generated revenue of $68.7 million, with a gross margin of 73.9% and a net loss of $60.8 million, for the year ended December 31, 2023 compared to revenue of $53.7 million, with a gross margin of 74.3% and a net loss of $58.9 million, for the year ended December 31, 2022. As of December 31, 2023, we had an accumulated deficit of $411.2 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. According to the World Health Organization, COPD is the third leading cause of death worldwide, causing 3.23 million deaths in 2019.

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 such as climbing a flight of stairs, walking, or showering, leading to a high mortality rate. We estimate that there are approximately 8.5 million severe COPD patients in developed markets globally as of 2019, and we estimate approximately 3.2 million have severe emphysema. 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.

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. 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 lung volume reduction surgery (“LVRS”), 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.

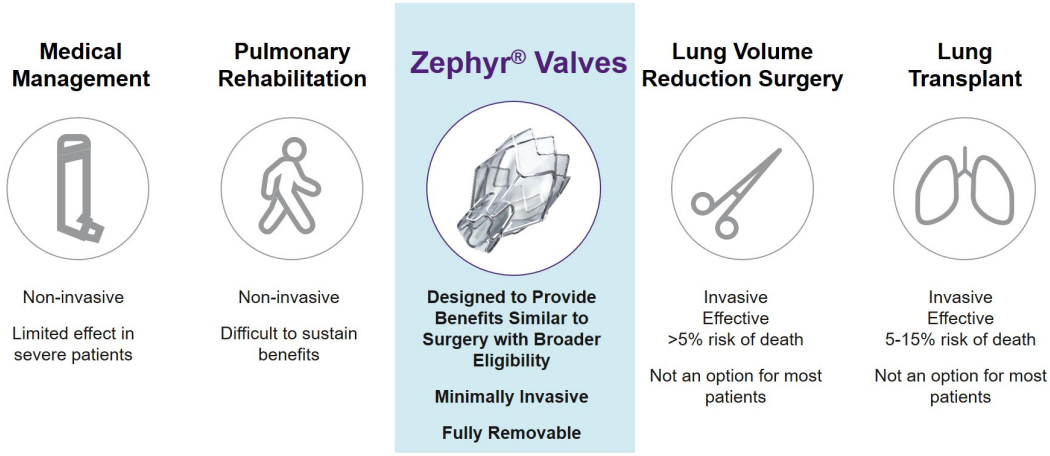
Lung transplantation involves surgically removing one or both lungs and replacing them with donor lungs. This procedure is highly time and resource intensive due to the complexity of the surgery. Even with a successful

procedure and consistent use of anti-rejection medications, lung transplantation patients have a five-year survival rate on average.

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.



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.

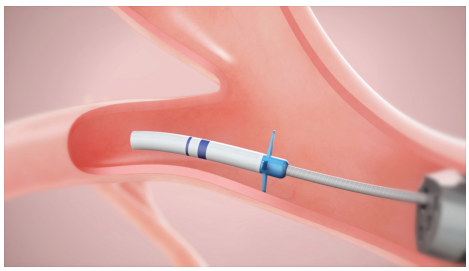
Placement of the Zephyr Valves

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

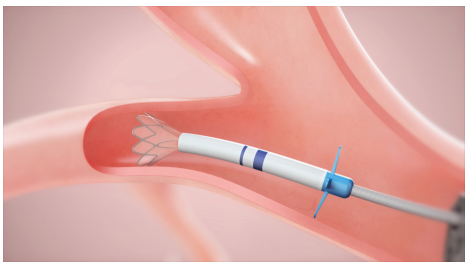
Each of the Zephyr Valves consists of a one-way silicone duckbill valve suspended inside a self-expanding frame made of shape-memory metal, called Nitinol. The Zephyr Valve is designed to be easily and accurately sized and offers controlled and accurate deployment at the target location. The Zephyr Valve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

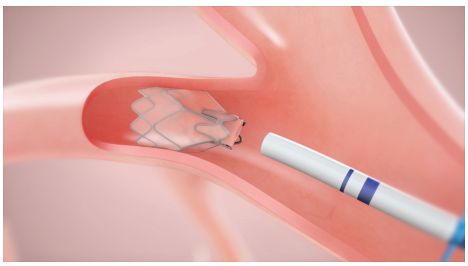
Physicians select the optimal valve size for each airway to be treated using an EDC that includes sizing wings and depth markers, which allows the physician to perform quick and accurate sizing.

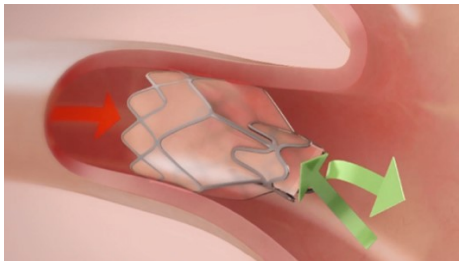


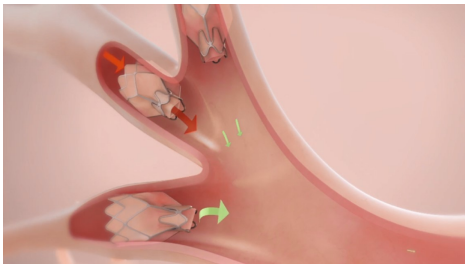
The Zephyr Valve is then loaded into the EDC.

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.

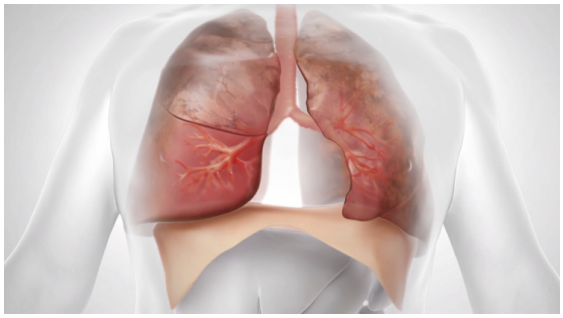








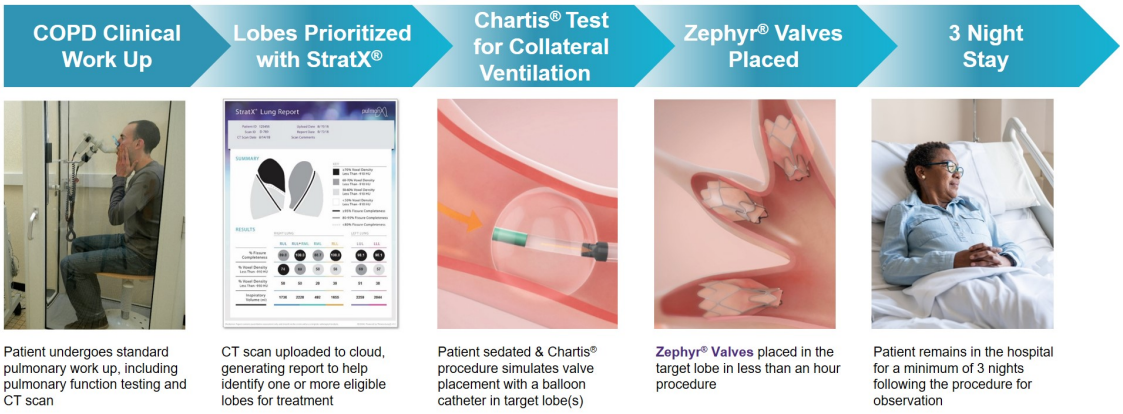
Once the lobe is fully obstructed, air vents out of the treated lobe and is unable to re-enter, causing a reduction in hyperinflation. The treated lobe shrinks in volume over time, allowing the remaining portions of the lung to expand and to restore diaphragm position, making breathing easier.



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

Treatment Steps

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



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 that includes information on emphysema destruction, fissure completeness and lobar volume to help identify target lobes for treatment with Zephyr Valves. 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 a third-party cloud service provider where it is analyzed using validated algorithms within the StratX Platform. The StratX Platform is designed to enable physicians to screen treatment

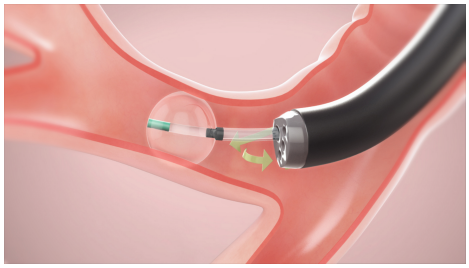
candidates non-invasively, prioritize between multiple potential treatment targets, if applicable, enhance case planning, and educate themselves and their patients using the simple-to-read StratX Lung Report.

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 successfully underwent a conformity assessment procedure with a Notified Body and was subsequently CE Marked in accordance with applicable legislation governing medical devices. 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.

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 has been validated in multiple randomized controlled clinical trials to predict likely 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 can be 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.

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.

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.

We have followed patients enrolled in the LIBERATE study for up to five years for safety and effectiveness (FEV_1) assessments. We have also established a patient registry to collect additional data on the safety and effectiveness (FEV_1) of the Zephyr Valve in the United States. We have established a similar registry in France and Japan.

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.

			Improvement in:		
Randomized Controlled Clinical Trials	**Size and Follow-up Period**	**Procedural Success (TLVR)** MCID ≥ 350mL	**Lung Function** (FEV_1%) ⊤ MCID ≥ 10%-15%	**Exercise Capacity** (6MWD) ⊤ MCID ≥ 26 m	**Quality of Life** (SGRQ) ⊤ MCID ≥ -4 pts
LIBERATE	n = 190 12 Mo	84%	18.0% p<0.001	39 m p=0.002	-7.1 pts p=0.004
TRANSFORM	n = 97 6 Mo	90%	29.3 % p<0.001	79 m p<0.001	-6.5 pts p=0.031
IMPACT	n = 93 6 Mo	89%	16.3 % p<0.001**	28 m p=0.016**	-7.5 pts p<0.001**
STELVIO	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 and is 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. 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.

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 and/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, nurses, respiratory therapists and pulmonary rehabilitation centers to raise awareness of Zephyr Valves as a treatment option.

Our strategy is to identify territories with high unmet need, identify leading hospitals and work with champions of our solution to establish quality Zephyr Valve programs. We believe there is a significant growth opportunity for hospitals to provide high quality comprehensive diagnosis and treatment for advanced COPD patients. We facilitate sharing of best practices among hospitals on how to efficiently educate stakeholders, screen patients, and manage patient care.

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 and Medscape, on continuing medical education-accredited training and with the American Lung Association and the COPD Foundation on patient and physician education. 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 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.

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 co-morbidities 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 80% of the potential Zephyr Valve patient population are Medicare/Medicaid beneficiaries with approximately 55% having managed Medicare/Medicaid and the remaining 45% having traditional fee-for-service Medicare/Medicaid. Approximately 20% of the potential Zephyr Valve patient population is under third-party commercial payor policies.

Commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, BCBS Michigan, and Highmark 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 payors 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.

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, Japan, 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.

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 Chartis assessment, valve deliverability and reduce procedure time and the use of AeriSeal 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 successfully undertaken the conformity assessment procedure in the EU with a Notified Body and CE marked AeriSeal on the basis of the MDD (as defined below), which we continue to place on the market in accordance with the transitional provisions of the MDR (as defined below), and have Therapeutic Goods Administration approval in Australia for the medical device 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. We have received a staged IDE approval to commence a clinical trial with AeriSeal. If successfully developed and approved, AeriSeal could further expand the addressable market of our solution.

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.

In addition to existing competitors, other companies may acquire or in-license competitive products and could directly compete with us.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2023, we had 35 patent families in force worldwide. As of December 31, 2023, we had rights to 65 issued United States patents, 15 pending United States patent applications, 112 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, StratX, 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 2024 and 2041. 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.

We also rely upon trademarks to build and maintain the integrity of our brand. As of December 31, 2023, we had nine registered trademarks, some of which 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. 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 terminate contemporaneously on September 30, 2024.

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. Several components used in our devices rely on single source suppliers and we routinely prioritize, evaluate and qualify backup sources. 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.

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 and Great Britain approved body, British Standards Institute ("BSI"), monitors compliance with the European Union Medical Devices Directive (Council Directive 93/42/EEC) ("MDD"), the Medical Device Regulation (Regulation (EU) 2017/745) ("MDR"), and the UK Medical Devices Regulations 2002 requirements through both annual scheduled audits and periodic unannounced audits of our manufacturing facilities as well as our contract third-party suppliers' facilities.

Our quality management system in our Redwood City manufacturing facility is currently ISO 13485:2016 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.

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 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.

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.

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.

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. 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.

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 the Medical Device Regulation (Regulation (EU) 2017/745) ("MDR").

On May 26, 2021, the MDR entered into application, repealing and replacing both the MDD, and Directive 90/385/EEC concerning active implantable medical devices, or AIMD. The MDR and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. Medical devices must comply with the General Safety and Performance Requirements, or GSPRs, set out in Annex I of the MDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPRs provided in the MDR and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The

Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming. After a device is placed on the market, it remains subject to significant regulatory requirements.

The MDR includes transitional provisions, amended by Regulation (EU) 2023/603. Accordingly, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD from May 25, 2017, and which remained valid on May 26, 2021 and have not since been withdrawn will, with certain exceptions, remain valid until December 31, 2027 for Class III and Class IIb implantable medical devices and until December 31, 2028 for other Class Iib, Class Iia and Class I devices with a measuring function or which are sterile. Class I medical devices, for which the conformity assessment procedure in accordance with the MDD or the AIMD did not require the involvement of a Notified Body but will require the involvement of a Notified Body in accordance with the MDR and for which an EU Declaration of Conformity was issued in accordance with the MDD or the AIMD prior to May 26, 2021, can continue to be placed on the EEA market until December 31, 2028. Manufacturers of medical devices may only benefit from the above extended transitional provisions deadlines if the following conditions are fulfilled: (i) the devices continue to comply with the requirements of the MDD or AIMD, (ii) there are no significant changes in the design and intended purpose, (iii) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, (iv) the manufacturer implements a quality management system by May 26, 2024 which complies with the requirements of the Medical Devices Regulation, (v) by May 26, 2024 an application is lodged with a Notified Body for conduct of the conformity assessment of the devices covered by the CE Certificate of Conformity, or the devices intended to substitute for such devices, in accordance with the MDR and a related written agreement is signed with the Notified Body by September 26, 2024, and (vi) from May 26, 2021, compliance with the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices is ensured in place of the corresponding requirements in the MDD or AIMD.

In addition, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD from May 25, 2017, which were valid on May 26, 2021 and have not been withdraw since but which expired before March 20, 2023, will only continue to be valid in accordance with the extended transitional deadlines above if either (i) the manufacturer signed a written agreement with a Notified Body for the conformity assessment of the device covered by the expired CE Certificate of Conformity, or the device intended to substitute that device, in accordance with the Medical Device Regulation before the date of expiry of the CE Certificate of Conformity, or (ii) a competent authority of an EU Member State has granted a derogation from the application conformity assessment procedure in accordance with Article 59(1) or Article 97(1) of the Medical Device Regulation.

The MDR sets out the regulatory framework for medical devices in the European Union. The Competent Authorities of each EU Member State oversee the implementation of the MDR within their jurisdiction. Devices are classified in accordance with their perceived risks in a manner similar to the United States risk classification system. Before a medical device can be marketed in the EU it must undergo a conformity assessment procedure after which the manufacturer may affix the CE mark on the devices. The class of a product determines the conformity assessment

required before the CE mark can be placed on a product. Our devices are Class IIa and Class IIb on the basis of the MDD and require the involvement of a Notified Body. Once the Notified Body has issued a Certificate of Conformity, the manufacturer has drawn up the Declaration of Conformity and affixed the CE mark the device can be sold throughout the European Union. We remain subject to ongoing MDR requirements including among others market surveillance after affixing the CE mark to our devices. We are currently placing our medical devices on the market in accordance with the MDR, as well as the stringent requirements of the transitional provisions of the MDR and the requirements of the MDD, as applicable to our products, and the guidance of the European Commission's Medical Devices Coordination Group. For those devices we are placing on the market in accordance with the transitional provisions of the MDR, we intend to complete conformity assessment procedures in accordance with the MDR prior to the expiration of our existing CE Certificate(s) of Conformity issued by our Notified Body BSI on the basis of the MDD, and the expiration of the transitional provisions of the MDR.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom, or the UK, was subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules continued to apply. The United Kingdom and the European Union have signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the United Kingdom and European Union's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the European Union and the UK in relation to goods. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a "third country," a country that is not a member of the European Union and whose citizens do not enjoy the European Union right to free movement. Northern Ireland will continue to follow many aspects of the European Union regulatory rules, particularly in relation to trade in goods, and including the MDR. In light of the fact that the CE Marking process is set out in EU law, which no longer applies in the United Kingdom, the United Kingdom has devised a new route to market culminating in a UKCA Mark to replace the CE Mark. Northern Ireland will, however, continue to be covered by the regulations governing CE Marks. The UK Government has established transitional provision to recognize the acceptance of CE marked medical devices on the Great Britain market. Accordingly, Class III and Class IIb implantable medical devices which have been CE marked in accordance with the MDD or AIMD and for which a CE Certificate of Conformity has been delivered by a Notified Body in accordance with the MDD or AIMD, can be placed on the Great Britain market until the sooner of the expiry of the related CE Certificate of Conformity or June 30, 2028. However, in light of the extended transitional provisions of the Medical Device Regulation, related CE Certificates of Conformity will expire, at the latest, on December 31, 2027. Other Class IIb, Class IIa and Class I devices with a measuring function which have been CE marked in accordance with the MDD or AIMD and for which a CE Certificate of Conformity has been delivered by a Notified Body in accordance with the MDD or AIMD, can be placed on the Great Britain market until the sooner of the expiry of the related CE Certificate of Conformity or June 30, 2028. Class I medical devices, for which the conformity assessment procedure in accordance with the MDD or the AIMD did not require the involvement of a Notified Body but will require the involvement of a Notified Body in accordance with the Medical Device Regulation and for which an EU Declaration of Conformity was issued in accordance with the MDD or the AIMD prior to May 26, 2021, can continue to be placed on the Great Britain market until June 30, 2028. Medical devices which have been CE marked in accordance with the Medical Device Regulation may be placed on the Great Britain market until June 30, 2030.

The UK government plans on introducing new legislation governing medical devices with an aim for core aspects of the future regime for medical devices to apply from July 1, 2025. New legislation is also anticipated in 2024 to bring into force strengthened post-market surveillance requirements ahead of the wider future regulatory regime. These post-market surveillance requirements are expected to apply from mid-2024. Our devices were regulated under MDD prior to Brexit and are subject to the *UK Medical Devices Regulations 2002.* Pulmonx has registered all products in accordance with the regulation, we received a related certificate of conformity from our Great Britain Approved Body BSI.

In addition, the advertising and promotion of medical devices in the EU is subject to the national laws of the individual EU Member States that implemented the MDD, the AIMD and that apply the MDR, Directive 2006/114/

EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EU Member States governing the advertising and promotion of medical devices. EU Member States' national legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

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"), and its implementing privacy and security regulations, established federal protection for the privacy and security of health information. HIPAA applies to Covered Entities 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. 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.

Privacy and Information Security Laws

In the ordinary course of our business, we may process personal data, including health data collected through the clinical trial process, our research collaborations, and directly from individuals or their healthcare providers under our patient reimbursement support programs. 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 and contractual obligations related to data privacy, security, and protection. Such obligations may include, without limitation, 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 United Kingdom ("UK") law (the "UK GDPR") (collectively, the "GDPR"). In addition, states within the United States have enacted data privacy laws including Virginia, Colorado, Utah, and Connecticut.

The CCPA and 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. 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, the California Privacy Rights Act of 2020 ("CPRA"), which became effective January 1, 2023, expands the CCPA by, among other things, giving California residents the ability to limit use of certain sensitive personal data, along with establishing restrictions on personal data retention and 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 GDPR, impose strict compliance obligations on entities for processing personal data, including health data. For example, the GDPR provides the competent authorities with extensive competences and powers to investigate and act against non-compliances or infringements including the potential to impose fines of up to €20 million under the EU GDPR, £17.5 million under the UK GDPR, or, in each case, 4% of the firm's worldwide annual revenue from the preceding financial year, whichever amount is higher.

The processing of personal health data of patients in the EU and the UK is subject to further stringent requirements. For example, such processing requires both a lawful basis under Article 6 GDPR and at least one separate condition

for processing under Article 9 GDPR. In addition, such processing must meet high standards under the GDPR regarding transparency and communication towards patients, identifying an appropriate legal basis for processing the personal data, purpose limitation and implementing appropriate technical and security measures safeguards for the transfer of personal data outside of the EU and the UK to countries like the USA, limiting personal data processing only to what is necessary, and increasing rights for data subjects.

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 Health and Human Services ("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.

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.

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. 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

Outside the United States, interactions between medical device companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct.

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.

United States Centers for Medicare and Medicaid Services ("CMS")

Medicare is a federal program administered by CMS through MACs. 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 MACs 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

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.

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. There have been executive, judicial and congressional challenges, and a number of health reform measures by the Biden administration that have impacted certain aspects of the Affordable Care Act. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. 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, will remain in effect until 2032 unless additional congressional action is taken.

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.

EU Health Reform

Moreover, in the EU some countries may, after the medical device is CE marked, require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medical devices, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It will apply from 2025.

Human Capital Management

Employees, Talent Management & Development

As of December 31, 2023, we had a total of 279 full time employees, with 213 employees in the U.S., 55 in Europe, and 11 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. We believe that our employees are the foundation of our business and we are committed to the development and retention of our workforce.

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.

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

Additionally, 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.

Health and Safety

The health and safety of our employees is a key focus at our Company. The Company is committed to protecting its employees everywhere it operates. The Company identifies potential workplace risks in order to develop measures to mitigate possible hazards.

Available Information

We were incorporated in the state of California on December 26, 1995 as Pulmonx and reincorporated in the state of Delaware on December 4, 2013. Our website address is 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, 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.

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, 2023 and 2022, we had net losses of $60.8 million and $58.9 million, respectively, and we expect to continue to incur additional losses. As of December 31, 2023, we had an accumulated deficit of $411.2 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, certification 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 the EU and other European countries 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 any public health crisis, such as a resurgence of COVID-19 infections, 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, certification 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, certification 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, 2023 and 2022 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. 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 a public health crisis, such as a resurgence of COVID-19 infections;
- 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, 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.

Public health crises, such as the COVID-19 pandemic, have in the past and may in the future have a material adverse impact on our business, financial condition and results of operations.

Public health crises, such as the COVID-19 pandemic, and other events beyond our control, have in the past and may in the future have a material adverse impact on our business, financial condition and results of operations. For example, the COVID-19 pandemic and related governmental and societal responses to mitigate its impact had a material adverse impact on our business, financial condition and results of operations by decreasing and delaying procedures performed using our products due to healthcare organizations prioritizing the treatment of patients with COVID-19 and altering their operations to respond to the pandemic.

A public health crises could significantly disrupt economic activity globally and have a material adverse impact our ability to access capital and on our business, financial condition and results of operations as a result of hospitals reducing capital and overall spend and other potential changes in healthcare organizations' prioritizing of patient treatment, significant job losses and unemployment, including the inability of patients to obtain or maintain health insurance policies, inflation, and reductions in disposable income. Additionally, if a public health crisis or other event beyond our control were to emerge, 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, and it may have the effect of heightening 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, 2023, commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, BCBS Michigan, and Highmark 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 prior authorization requests on a case-by-case basis.

The Centers for Medicare & Medicaid Services (“CMS”) have established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a

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

Physicians that insert the Zephyr Valve, or the hospitals for which they work, may be subject to reimbursement claim denials upon submission of the claim. Physicians or hospitals may also be subject to recovery of overpayments if a payor makes payment for the claim and subsequently determines that the payor's coding, billing or coverage policies were not followed. Whenever possible, prior authorization for coverage for the procedure is recommended before the procedure is performed. When prior 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 market access in countries across Europe and Asia Pacific, including Australia, Austria, Belgium, France, Germany, Japan, 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. For example, in some markets, such as France, coverage and reimbursement are currently available for procedures using our products but are subject to constraints such as price controls or unit sales limitations.

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 may generate in the future will be consistent with that observed in our existing clinical studies.

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

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

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase the number of customers and emphysema centers of excellence. Identifying and recruiting qualified sales and marketing personnel and training them on our solution, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing techniques or products that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our solution. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our solution will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our solution in a cost-effective manner is critical to achieving broad acceptance of our solution and expanding domestically and internationally. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our solution.

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

Although we have demonstrated the safety, effectiveness and clinical advantages of our solution in multiple clinical trials in approximately 450 patients selected using the Chartis System, the Zephyr Valve is still a relatively new treatment for severe emphysema. The long-term effects of using our solution in a large number of patients are currently being 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 were 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. Patient follow up for this extension study has been recently completed, and data analysis is ongoing. Our ability to interpret the data from the LIBERATE extension study may be limited by the fact that the matched control group exited the study after one year. In addition to the LIBERATE extension study, registry studies evaluating the safety and effectiveness of our solution out to three years in the United States, France and Japan are ongoing, with a total enrollment of over 300 patients. 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, certification 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 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;
- our failure to increase production capacity or volumes to meet demand;
- our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

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

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

To ensure adequate inventory supply, we must forecast inventory needs and manufacture the Zephyr Valve and Chartis System based on our estimates of future demand for our solution. Our ability to accurately forecast demand for our solution could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our solution or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our solution, our internal manufacturing team may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are

acceptable to us, or at all, or suppliers or may not be able to allocate sufficient capacity in order to meet our increased requirements, which will negatively affect our business, financial condition and results of operations.

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

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

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

- the level of demand for our products and any 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, certification 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 rate at which treating centers expand procedural capacity as they build a bronchoscopic lung volume reduction program;
- 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 impact of a public health crisis, such as a resurgence of COVID-19 infections, on our business, financial condition and results of operations;
- 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 which are subject to macroeconomic factors including inflation;
- the number of patients treated with Zephyr Valves, including 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 an 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 could 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 and cyber insurance 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. 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 March 2021, we entered into an Amended and Restated Loan and Security Agreement (as amended, the "CIBC Agreement") with Canadian Imperial Bank of Commerce ("CIBC"), under which we have borrowed $37.0 million in debt financing as of December 31, 2023. See the section entitled "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 the sale of equity securities, debt financing arrangements and sales of our products. As of December 31, 2023, we had $131.5 million in cash, cash equivalents and marketable securities, and an accumulated deficit of $411.2 million. Based on our current planned operations, we expect our cash, cash equivalents and short-term marketable securities 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 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;
- 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; and
- the impact of public health crises, such as a resurgence of COVID-19 infections, on our business, financial condition, and results of operations.

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, the rest of our senior management, and other key personnel. From time to time, there have been and may in the future be changes in our management team or other key employees resulting from the hiring or departure of these personnel. Although we have entered into employment letter agreements with 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. 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 33.1% and 39.5% of our revenue for the years ended December 31, 2023 and 2022, respectively. We currently focus our international sales and marketing efforts in Australia, Austria, Belgium, China, Denmark, France, Germany, Ireland, Italy, Japan, 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;
- the impact of public health crises, such as a resurgence of COVID-19 infections;
- 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.

A public health crisis, such as a resurgence of COVID-19 infections, 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, they may negatively affect our business, financial condition and results of operations.

If our information technology systems or data, or those third parties upon which we rely, are 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 business, we or the third parties upon whom we rely, collect, store, receive, generate, use, transfer, disclose, make accessible, protect, secure, dispose of or transmit (collectively, "process") proprietary, confidential, and sensitive data (including but not limited to intellectual property, proprietary business information and personal data).

We rely extensively on information technology ("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. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Although we have implemented policies and procedures designed to ensure compliance with applicable data privacy and information security laws and regulations and we take measures to protect sensitive information from unauthorized access or disclosure, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our IT systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Unremediated high risk or critical vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our 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," threat actors, "hacktivists," organized criminal threat actors, personnel misconduct or error (such as theft or misuse), sophisticated nation-state and nation-state supported actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon whom we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems, operations and supply chain.

Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. 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.

Although the aggregate impact of security 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 security 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 related to 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 incidents, it may result in: government enforcement actions that could include investigations, fines, penalties, consent decrees, 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 information security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors 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.

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. There can be no assurance that limitations of liability in our contracts are sufficient or adequate enough to protect us from liabilities, damages, or claims related to our security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative artificial intelligence ("AI") technologies.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

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, including as a result of geopolitical conflict, 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 inflationary pressures, could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing will negatively affect our business, financial condition and results of operations and we cannot anticipate all of the ways in which the economic climate and financial market conditions could negatively affect our business, financial condition and results of operations.

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

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our current business, enhance our technical capabilities or otherwise offer growth opportunities. Accordingly, although we have no current commitments with respect to any acquisition or investment, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, applications or technologies instead of developing them ourselves. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or

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

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

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

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

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

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

- assemble sufficient resources to acquire or discover additional products;
- properly identify and anticipate physician and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from pre-clinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications;
- be fully compliant with FDA and comparable foreign regulatory authorities' requirements relating to the 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. Foreign currency exchange fluctuations have negatively impacted, and may continue to negatively impact, our revenue from international markets. 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 comparable foreign regulatory authorities abroad. 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.

The 510(k) or PMA and foreign equivalents process can be expensive, lengthy and unpredictable. We may not be able to obtain any necessary clearances, certification 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, certification 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 and CE marked our product after obtaining related CE Certificates of Conformity to market the Zephyr Valve, our approval can be revoked if safety or efficacy problems develop.

The FDA, comparable foreign regulatory authorities and Notified Bodies can delay, limit or deny clearance, certification or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA, the applicable regulatory authority or Notified Body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory authority or Notified Body with the design or implementation of our clinical 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, certification 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 authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance, certification or approval.

If we fail to remain in compliance with applicable European Union laws, 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") and other European countries in which we rely on the CE mark.

The FDA and state and international authorities including EU Member States have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency and authority, 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, certification or premarket approval of new products or services, new intended uses or modifications to existing products or services;
- withdrawal of regulatory clearance, certification 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.

In addition to changes to the regulatory environment in the United States, there have been changes to the regulatory environment in certain foreign jurisdiction in which we operate. For example, the MDR became applicable in 2021 and includes transitional provisions. We are currently placing our medical devices on the market in accordance with the stringent requirements of the transitional provisions of the MDR, the requirements of the MDD and the guidance of the European Commission's Medical Devices Coordination Group. We intend to complete conformity assessment procedures for our medical devices in accordance with the MDR prior to the expiration of our existing CE Certificate(s) of Conformity issued by our Notified Body BSI on the basis of the MDD, and the expiration of the transitional provisions of the MDR. The changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations for medical devices we intend to place on the EU market, or our Notified Body, where they are involved, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the MDR. We must obtain the appropriate CE Certificate(s) of Conformity in accordance with the MDR to continue to place our products on the EU market, or other countries that relate their medical device regulations to a CE mark, once we can no longer benefit from the transitional provisions of the MDR. The modifications of the MDR may have an effect on the way we conduct our business in the EEA. Additional regulatory changes may negatively affect our business, financial condition and results of operations.

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. If a prolonged government shutdown occurs, or if global health concerns 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 regulatory 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 regulatory 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 authorities 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 regulatory 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. Comparable requirements and related consequences are applicable in foreign countries.

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 or entity 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 FCA, 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, the UK and other jurisdictions, including national anti-bribery laws of European countries and national rules, regulations, industry self-regulation codes reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as personal data under the GDPR.

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 FCA.

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.

In December 2022, we received a civil investigative demand ("CID") from the U.S. Department of Justice, Civil Division in connection with an investigation under the Anti-Kickback Statute and False Claims Act (the "Investigation"). The CID requests information and documents regarding our relationships with certain health care providers, medical practices, and hospitals in connection with the sales and marketing of the Zephyr Valves and related products and services. We are fully cooperating with the Investigation. We are unable to express a view at this time regarding the ultimate outcome of the Investigation or estimate an amount or range of reasonably possible loss. Depending on the outcome of the Investigation, there could be a material impact on our business, results of operations and financial condition.

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 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, or comparable foreign programs, imprisonment, contractual damages, reputation harm and disgorgement and we could be required to curtail or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

If we modify the Zephyr Valve, we may need to seek additional clearances, certification 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.

For those medical devices sold in the EU and for which we have obtained a CE Certificate of Conformity by a Notified Body, we must notify our Notified Body if significant changes are made to the devices or if there are substantial changes to our quality assurance systems affecting those products. In addition, if we make any substantial changes to medical devices for which we have obtained a CE Certificate of Conformity on the basis of the MDD and which we continue to place on the EU market on the basis of the transitional provisions of the MDR, we will no longer be able to benefit from the transitional provisions of the MDR. Substantial changes to such devices will trigger immediate compliance with the full regulatory framework of the MDR.

Delays in receipt or failure to receive approvals or certifications, the loss of previously received approvals or certifications, 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. In the EU, the MDR also imposes strict post-market regulatory requirements which are also applicable to those devices for which we have obtained a CE Certificate of Conformity on the basis of the MDD and which we continue to place on the EU market on the basis of the transitional provisions of the MDR.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory approval or certification to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. 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 or comparable foreign regulatory authorities, or certification from Notified Bodies, 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 or comparable foreign regulatory authorities, or certification from Notified Bodies. 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, including Quality Management System requirements, 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 comply with ongoing International Organization for Standardization ("ISO") 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, competent authorities of EU Member States, European Union Notified Bodies and comparable authorities 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, certification 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. We believe that we are in compliance, in all material respects, with the QSR.

We also maintain CE Certificate of Conformity for the design and manufacture of our products issued by BSI in the Netherlands, our European Notified Body, in accordance with the MDD and MDR, as applicable to our products. We believe that we are in compliance, in all material respects, with the MDD and MDR, as applicable to our products.

We can provide no assurance that we will continue to remain in compliance with the QSR, MDR, and MDD, as applicable to our products. If the FDA, CDPH, BSI or competent authorities of EU Member States 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, or for which we have CE marked our products, 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, or for which we have CE marked our products. Use of a device outside of its cleared, approved, or CE marked indications is known as "off-label" use. Physicians may use our products off-label in their professional medical judgment, as the FDA and comparable foreign regulatory authorities do not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA or comparable foreign regulatory authorities determine 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 authority 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 FCA, 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 and certification is lengthy and expensive with uncertain outcomes. If clinical studies of our future products do not produce results necessary to support regulatory clearance, certification 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. Similar requirements may apply outside the U.S. 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 or comparable foreign regulatory authorities 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, certification or approval of our products. The data we collect from our pre-clinical studies and clinical trials may not be sufficient to support FDA or comparable foreign regulatory authority clearance or approval, or certification, 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, certification 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. Similar requirements may apply outside the U.S. 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 or comparable foreign approvals or certification. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for approvals, certification or clearances of new product lines, or for the approval or certification 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, or comparable foreign applications, which must become effective prior to commencing human clinical trials, and the FDA or comparable foreign regulatory authorities may reject our 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, ethics committees or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations ("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, vary 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, ethics committee or regulatory authority for re-examination;
- regulators, IRBs, ethics committees, or other parties may require or recommend that we or our investigators suspend, vary 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, ethics committees 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 authorities 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 authorities and IRBs or ethics committees at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice, 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, certification or approval by regulatory authorities in those countries. Clearance, certification 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 comparable foreign regulatory authorities, 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, national competent authorities of EU Member States and comparable foreign regulatory authorities, including reports required by the MDRs and the (EU) MDR 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 authorities. This report could be classified by the FDA or comparable foreign regulatory

authorities as a device recall which could lead to increased scrutiny by the FDA, other foreign regulatory authorities 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, certification 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, certification or approvals, can be expensive and time-consuming, and we may not receive regulatory approvals or certification 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, certification or approvals, if required by other countries, may be longer than that required for FDA approval, and requirements for such registrations, clearances, certification or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory approvals or certification before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations or certification that we have received. If we are unable to maintain our authorizations or certification 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, certification or approval by regulatory authorities in other countries, and registration, clearance, certification 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, certification 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 that continue to impact the healthcare industry.

There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (“IRA”) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a

newly established manufacturer discount program. 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, will remain in effect until 2032 unless additional congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The 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.

We are subject to stringent and evolving 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; loss of revenue or profits; and other adverse business impacts.

In the ordinary course of business, we or the third parties upon whom we rely, may collect, store, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share or otherwise process proprietary, confidential, and sensitive data (including but not limited to intellectual property, proprietary business information and personal data).

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 information security obligations, such as external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data 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 data privacy and information security laws are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, the CCPA went into effect on January 1, 2020 and requires companies that process personal data 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. In addition, the CPRA, which became effective on January 1, 2023, expands the compliance requirements and rights available to consumers under the CCPA. The CPRA also establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. As such, the CPRA may require additional compliance investment and potential business process changes in the meantime. Other states, such as Virginia, Colorado, Utah and Connecticut, have also passed comprehensive data privacy laws, and similar laws are being considered in several other states. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy and information security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive data, such as personal data, 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.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the GDPR governs the processing (which can include any action, such as collection, use, storage adaptation or alteration, disclosure or transfer) of personal data relating to individuals located in Europe (including the UK). 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 to justify data processing activities; granting various rights for data subjects in regard to their personal data, such as the right to delete certain 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, £17.5 million, or, in each case, 4% of our global turnover, whichever is greater). 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.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to

regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personal data 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 and information security 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 information security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and information security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Moreover, complying with the various data privacy and information security 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. In addition, these obligations may require us to change our business model. 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.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed or enacted laws governing AI/machine learning ("ML"). For example, European regulators have proposed a stringent AI regulation, and we expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

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 data, 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 GDPR and national legislation of European Union Member States or the UK.

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, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, or comparable foreign 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;
- 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 inflation, rising interest rates, economic recessions or economic slowdowns;
- changes in the structure of healthcare payment systems; and
- developments or disputes concerning our intellectual property or other proprietary rights.

Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small expected public float of shares of our common stock on the Nasdaq Global 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.

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

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

We are currently a "smaller reporting company" and our compliance with the scaled reporting and disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.

We are a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act. As a result, we may take advantage of certain scaled disclosures available to smaller reporting companies, and we may take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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.

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 and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and 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 any 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, which could seriously harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and critical data, including intellectual property, and confidential information that is proprietary, strategic or competitive in nature ("Information Systems and Data").

Our assessment, identification and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. We rely on a multidisciplinary team, including our information technology department, legal department, management, engineering operations, and third-party service providers (the "Security Function") to help assess, identify and manage the Company's cybersecurity threats and risks. Various members of the Security Function monitor and evaluate our cybersecurity threat environment using various methods including, for example, using manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and threat actors, conducting scans of the threat environment, and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards, and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, an incident response plan, risk assessments, incident detection and response, vulnerability management, encryption of data, network security controls, data segregation, access controls, physical security, systems monitoring, employee training, cybersecurity insurance, and asset management, tracking and disposal.

We work with third-parties from time to time to assist us to identify, assess, and manage risks from cybersecurity threats, including, for example, professional services firms, including outside legal counsel, cybersecurity consultants, and cybersecurity software providers.

We use certain third-party service providers to perform a variety of functions that help us operate our business, such as application providers, hosting companies, contract research organizations, distributors, and supply chain resources. Depending on the nature of the services provided, the sensitivity and information processed, and the identity of the service provider, our vendor management process may include different levels of assessment designed to help identify cybersecurity risk associated with a provider. Such assessments include, for example, reviewing the written security program of such provider and conducting security assessments and audits.

See Part I, Item 1A, "Risk Factors" for a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, including the risk factor titled, *If our information technology systems or data, or those third parties upon which we rely, are 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*.

Governance

Our board of directors address the Company's cybersecurity risk management as part of its general oversight function. The board of directors' Audit Committee is responsible for overseeing the Company's cybersecurity risk management processes, including the Company's oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of Company management, including the Senior Director of Information Technology, who has worked in various roles responsible for securing networks and application systems, the Chief Executive Officer, the General Counsel, the Interim Chief Financial Officer, and the VP of Finance and Administration. These members of management are responsible for hiring appropriate personnel, integrating cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. They are also responsible for approving budgets, helping to prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. When incidents are identified, these members of management are responsible for determining whether such incidents are material and may escalate material incidents to the Audit Committee and/or investors, based on the particular circumstances.

The Audit Committee receives periodic updates from management concerning the Company's significant cybersecurity threats, risks, and the processes the Company has implemented to address them. In addition, the Audit Committee and management maintain an ongoing dialogue regarding emerging or potential cybersecurity risks.

ITEM 2. PROPERTIES

Our corporate headquarters are 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. Please see also the matters under the caption Contingencies in Note 8 to the consolidated financial statements.

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 19, 2024, there were approximately 136 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

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. As of December 31, 2023, we had used all the net proceeds from our IPO of approximately $201.4 million.

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.

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.

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 96% of our revenue generated in markets where we sell directly for the year ended December 31, 2023.

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 prior 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, South Korea and Japan.

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 $68.7 million, with a gross margin of 73.9% and a net loss of $60.8 million, for the year ended December 31, 2023 compared to revenue of $53.7 million, with a gross margin of 74.3% and a net loss of $58.9 million, for the year ended December 31, 2022. As of December 31, 2023, we had an accumulated deficit of $411.2 million, cash, cash equivalents and marketable securities of $131.5 million, and $37.2 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.

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, BCBS Michigan, and Highmark 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 prior 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 prior 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, South Korea and Japan.

Competition

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

Leveraging Our Manufacturing Capacity is Critical to Improving Our Gross Margin

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

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

We intend to continue investing in existing and next generation technologies to further improve our products and clinical outcomes, enhance patient selection and broaden the patient population that can be treated with our products.

In addition, we are continuing to invest in the accuracy and features of our patient assessment tools. Moreover, we 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, primarily in the first and third quarters and anticipate this trend to continue. In addition, as our sales grow, we may experience further 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, 2023 and 2022.

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, and charges for excess, obsolete and non-sellable inventories. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision and management and an allocation facilities overhead cost, including rent and utilities. Cost of goods sold also includes 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, consulting services, clinical trial expenses, prototyping, testing, laboratory supplies, and an allocation of facility overhead costs. Our clinical trial expenses, such as those related to our AeriSeal clinical development program, include costs associated with clinical trial design, clinical trial site development and study costs, data management costs, related travel expenses and the cost of products used for clinical activities. 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, finance and 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. Additionally, we incur 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 2020 Equity Incentive Plan and related grants either in the form of restricted stock units or stock 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 foreign currency exchange gains and losses.

Results of Operations:

Comparison of the Years Ended December 31, 2023 and December 31, 2022

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

	Years Ended December 31,			
	2023	2022	$ Change	% Change
	(in thousands)			
Revenue	$ 68,675	$ 53,662	$ 15,013	28.0 %
Costs of goods sold	17,923	13,797	4,126	29.9 %
Gross profit	50,752	39,865	10,887	27.3 %
Operating expenses:				
Research and development	18,080	15,397	2,683	17.4 %
Selling, general and administrative	94,607	83,105	11,502	13.8 %
Total operating expenses	112,687	98,502	14,185	14.4 %
Loss from operations	(61,935)	(58,637)	(3,298)	5.6 %
Interest income	5,568	1,529	4,039	264.2 %
Interest expense	(3,232)	(1,066)	(2,166)	203.2 %
Other income (expense), net	(673)	(396)	(277)	69.9 %
Net loss before tax	(60,272)	(58,570)	(1,702)	2.9 %
Income tax expense	571	353	218	61.8 %
Net loss	$ (60,843)	$ (58,923)	$ (1,920)	3.3 %

Revenue

Revenue increased by $15.0 million, or 28.0%, to $68.7 million during the year ended December 31, 2023, compared to $53.7 million during the year ended December 31, 2022. The sale of products in the United States increased by $13.4 million to $45.9 million during the year ended December 31, 2023, compared to $32.5 million for the year ended December 31, 2022. The sale of products in international markets increased by $1.6 million to $22.8 million during the year ended December 31, 2023, compared to $21.2 million for the year ended December 31, 2022. The increase in revenue reflects continued growth of Zephyr Valve procedure volumes in the United States and in international markets.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased by $4.1 million, or 29.9%, to $17.9 million during the year ended December 31, 2023, compared to $13.8 million during the year ended December 31, 2022. The increase was mainly due to an increase in the number of products sold and increased manufacturing costs as we invested to support anticipated growth. Gross margin was 73.9% during the year ended December 31, 2023, compared to 74.3% during the year ended December 31, 2022.

Research and Development Expenses

Research and development expenses increased by $2.7 million, or 17.4%, to $18.1 million during the year ended December 31, 2023, compared to $15.4 million during the year ended December 31, 2022. The increase in research

and development expenses was primarily due to an increase of $0.9 million in costs associated with our clinical trials, including fees paid to contract research organizations and testing expenses, an increase of $0.8 million in payroll and personnel-related expenses including stock-based compensation, and an increase of $0.8 million in professional services and other expenses in support of product development.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $11.5 million, or 13.8%, to $94.6 million during the year ended December 31, 2023 compared to $83.1 million during the year ended December 31, 2022. The increase in selling, general and administrative expenses was primarily due to an increase of $11.4 million in payroll and personnel-related expenses including stock-based compensation for our sales, marketing and administrative personnel, and an increase of $1.3 million in legal and other professional expenses, offset by a decrease of $1.4 million in advertising and marketing related expenses.

Interest Expense and Income

Interest expense increased by $2.2 million, or 203.2%, to $3.2 million during the year ended December 31, 2023, compared to $1.1 million during the year ended December 31, 2022 due to higher outstanding debt principal and higher interest rates. Interest income increased by $4.0 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to higher returns on cash, cash equivalents and marketable securities balances.

Other Income (Expense), Net

Other income (expense), net decreased by $0.3 million to ($0.7) million during the year ended December 31, 2023, compared to ($0.4) million during the year ended December 31, 2022, primarily due to foreign currency exchange losses driven by fluctuations in foreign exchange rates.

Liquidity and Capital Resources; Plan of Operation

To date, we have financed our operations primarily through our IPO, private placements of equity securities, debt financing arrangements and sales of our products. As of December 31, 2023, we had cash, cash equivalents and marketable securities of $131.5 million, an accumulated deficit of $411.2 million, and $37.2 million outstanding under the CIBC Loan and Credit Agreement, net of debt discount and debt issuance costs.

CIBC Loan

On February 20, 2020, we executed a Loan and Security Agreement with Canadian Imperial Bank of Commerce (“CIBC”), which we subsequently amended on April 17, 2020 and December 28, 2020 (as amended, the “CIBC Agreement”). The CIBC Agreement originally provided us with the ability to borrow up to $32.0 million in debt financing consisting of $17.0 million advanced at the closing of the agreement (“Tranche A”), with the option to draw up to an additional $8.0 million (“Tranche B”) on or before February 20, 2022 and an additional $7.0 million (“Tranche C”) on or before February 20, 2022. Neither Tranche B nor Tranche C was drawn before the February 2022 expiration date.

In March 2021, we entered into an Amended and Restated Loan and Security Agreement with CIBC (as amended, the “Amended and Restated CIBC Agreement”) which, among other things, extended the loan maturity date under the CIBC Agreement from March 15, 2022 to February 20, 2025, and modified certain financial covenants.

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

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

In October 2022, we entered into a Third Amendment to the Amended and Restated CIBC Agreement (the "Third Amendment"), which, among other things, extended the maturity date to October 31, 2027; provided a commitment for a new $20.0 million tranche of term loans that may be drawn at the Company's option through October 31, 2023, subject to the satisfaction of certain conditions; and provided for a new interest only period of 24 months from the signing date of the Third Amendment, with the possibility of an additional extension of such interest only period of up to 12 months, subject to satisfaction of certain conditions.

In February 2023, we drew $20.0 million of the Amended Tranche B of the CIBC Loan. The Amended Tranche B bears interest at a floating rate equal to 1.0% above the Wall Street Journal Prime Rate and has the same repayment terms as Tranche A.

The loans provided under the Amended and Restated CIBC Agreement bear interest at a floating rate equal to 1.0% above the Wall Street Journal Prime Rate at any time. The loan is collateralized by substantially all of our assets, including cash and cash equivalents, accounts receivable, intellectual property and equipment. We may prepay the loans, subject to certain conditions, including a prepayment fee equal to 2.0% of the principal amount prepaid during the first year after the effective date of the Third Amendment or 1.0% of the principal amount prepaid during the second year after the effective date of the Third Amendment. The Amended and Restated CIBC Agreement contains financial covenants that require the Company to maintain minimum cash and minimum revenue amounts, and the Amended and Restated CIBC Agreement contains other customary restrictive covenants, representations and warranties, events of default and other customary terms and conditions.

We paid $0.5 million fees to the lender and third parties which is reflected as a discount on the loans provided under the Amended and Restated CIBC Agreement and is being accreted over the life of the loan using the effective interest method. During the years ended December 31, 2023 and December 31, 2022, we recorded interest expense related to debt discount and debt issuance costs of CIBC Loan of less than $0.1 million and $0.1 million, respectively.

Interest expense on the CIBC Loan amounted $3.2 million and $1.1 million during the years ended December 31, 2023 and December 31, 2022, respectively.

Credit Agreement

In May 2020, Pulmonx International Sàrl, our wholly-owned subsidiary, received 0.5 million Swiss Francs ($0.5 million U.S. dollar equivalent) from a COVID-19 Credit Agreement under a Swiss Federal Government program designed to mitigate the economic impact of the spread of the coronavirus. The COVID-19 Credit Agreement initially bore no interest through March 31, 2023. Beginning April 1, 2023, the loan bears interest at a rate of 1.5% per year, payable at the end of each calendar quarter. The loan principal is being repaid in twelve equal installments, paid semi-annually, which began in March of 2022. Interest expense was immaterial during the year ended December 31, 2023. Pulmonx International Sàrl repaid $0.1 million and $0.1 million to the lender during the years ended December 31, 2023 and December 31, 2022, respectively.

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:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (37,610)	$ (45,083)
Investing activities	(2,007)	(4,225)
Financing activities	21,400	2,419
Effect of exchange rate changes on cash and cash equivalents	34	145
Net decrease in cash, cash equivalents and restricted cash	$ (18,183)	$ (46,744)

Cash Flows from Operating Activities

Net cash used in operating activities was $37.6 million for the year ended December 31, 2023. Cash used in operating activities was primarily a result of the net loss of $60.8 million, a decrease in lease liabilities of $3.2 million due to lease payments, an increase in accounts receivable of $3.1 million due to revenue growth and the timing of payments from our customers, net accretion of discounts on marketable securities of $1.0 million, and a decrease in accounts payable of $0.3 million due to timing of payments to our vendors, partially offset by an increase in accrued liabilities of $3.2 million due to increased accrued incentive compensation expense associated with the achievement of performance objectives, a decrease in inventory of $0.9 million, stock-based compensation expense of $22.1 million, non-cash lease expense of $2.7 million, depreciation and amortization expense of $1.5 million and write-down of inventory of $0.5 million.

Net cash used in operating activities was $45.1 million for the year ended December 31, 2022. Cash used in operating activities was primarily a result of the net loss of $58.9 million, an increase in inventory of $3.6 million due to continued production to build inventory to meet projected increase in sales and to protect against potential supply interruptions, an increase in accounts receivable of $2.2 million, and a decrease in lease liabilities of $2.2 million due to lease payments, partially offset by an increase in accounts payable of $0.2 million due to timing of payments to our vendors, and a decrease in prepaid expenses and other current assets of $0.8 million, stock-based compensation expense of $16.4 million, non-cash lease expense of $2.5 million, depreciation and amortization expense of $1.5 million and write-down of inventory of $0.5 million.

Cash Flows from Investing Activities

Net cash used in investing activities in the year ended December 31, 2023 was $2.0 million consisting of purchases of marketable securities of $46.2 million and purchases of property and equipment of $0.8 million partially offset by proceeds from maturities of marketable securities of $45.0 million.

Net cash used in investing activities in the year ended December 31, 2022 was $4.2 million consisting of purchases of marketable securities of $47.2 million and purchases of property and equipment of $1.3 million partially offset by proceeds from maturities of marketable securities of $44.3 million.

Cash Flows from Financing Activities

Net cash provided by financing activities in the year ended December 31, 2023 of $21.4 million primarily relates to proceeds of $20.0 million from borrowing under the Amended and Restated CIBC Agreement, proceeds from issuance of common stock under the employee stock purchase plan of $1.2 million and proceeds from exercise of

common stock options of $0.3 million, partially offset by repayment of debt under the Credit Agreement of $0.1 million.

Net cash provided by financing activities in the year ended December 31, 2022 of $2.4 million primarily relates to proceeds from the exercise of stock options of $0.6 million and proceeds from issuance of common stock under the employee stock purchase plan of $1.9 million, offset by repayment of debt under the Credit Agreement of $0.1 million.

Material Cash Requirements

Our net cash operating expenditures were $37.6 million during the year ended December 31, 2023 and $45.1 million during the year ended December 31, 2022, 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 $0.8 million during the year ended December 31, 2023 and $1.3 million during the year ended December 31, 2022, and we expect to maintain the level of 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 $4.3 million at December 31, 2023, with $3.2 million expected to be paid within the next 12 months, and amounts related to future short-term and long-term debt which totaled $45.7 million, with $5.7 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, 2023, we had cash, cash equivalents and marketable securities of $131.5 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, 2023. 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. Our future funding requirements will depend on many factors, including:

- the costs of commercialization activities related to commercializing our products in the United States and elsewhere, including expanding territories, increasing sales and marketing personnel, actual and anticipated product sales, marketing programs, manufacturing and distribution costs;
- the impact of any public health crises, such as a resurgence of COVID-19 infections, on our business, financial condition and results of operations;
- 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 and estimates discussed below are critical to understanding our historical and future performance, as these 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 primarily from the sale of our products to hospitals and distributors 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 product 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.

We review our inventories for classification purposes. The value of inventories not expected to be realized in cash, sold or consumed during the next 12 months are classified as long-term inventory.

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 contract 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.

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 our historical volatility and 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.

As of December 31, 2023, there was $43.7 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 2.5 years.

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

We are exposed to certain market risks in the ordinary course of our business. Our market risk exposure is primarily a result of exposure resulting from interest rates, currency exchange rates, and effects of inflation.

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 $83.5 million as of December 31, 2023, which consist of cash and money market funds. We held cash in foreign banks of approximately $4.7 million at December 31, 2023 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 $36.8 million under the CIBC Agreement with an annual effective interest rate of 10.1% as of December 31, 2023. 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 33.1% and 39.5% of our total revenue for the year ended December 31, 2023 and 2022, 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, 2023 by approximately $2.3 million and $1.9 million, respectively, with a net impact of $0.4 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.

Inflation Risk

High inflation rates in the U.S. and overseas have resulted in increased transportation, wages, and other costs. Inflation may generally affect us by increasing our cost of labor, commercial support, manufacturing and clinical trial expenditures. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, if our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs with increased revenues. Our inability or failure to do so could harm our business, financial condition, and results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Pulmonx Corporation

INDEX TO THE FINANCIAL STATEMENTS

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, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory Classification

Inventory totaled approximately $19.3 million at December 31, 2023, including approximately $2.6 million classified as long-term inventory. As described in Note 2 to the Company's financial statements, the value of inventories not expected to be realized in cash, sold or consumed during the next 12 months are classified as long-

term inventory. Management considers forecasted demand and other expected usage of inventory on hand when estimating long-term inventory.

We identified management's estimation of forecasted demand for products used in the determination of long-term inventory classification to be a critical audit matter. Management is required to make significant judgments and assumptions with respect to future demand for the Company's products that affect the estimation of long-term inventory. Auditing these elements involved especially challenging and subjective auditor judgment and an increased extent of effort.

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

- Evaluating management's ability to accurately forecast the future demand for products by performing a retrospective comparison of the Company's prior forecasts to actual results for the same period.

- Evaluating the reasonableness of management's forecasted demand for products, by comparing forecasts to (i) historical sales of the Company's products, and (ii) forecasted information included in Company's press releases.

- Evaluating whether forecasted demand for products is consistent with evidence obtained in other areas of the audit.

- Assessing whether any known or knowable factors occurred subsequent to year end that impact management's forecast of future inventory usage.

/s/ BDO USA, P.C.

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

San Francisco, California

February 27, 2024

Pulmonx Corporation

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 83,547	$ 101,736
Restricted cash	237	231
Short-term marketable securities	33,555	39,402
Accounts receivable, net	12,105	8,677
Inventory	16,743	14,564
Prepaid expenses and other current assets	4,235	4,343
Total current assets	150,422	168,953
Long-term marketable securities	14,390	5,924
Long-term inventory	2,580	5,283
Property and equipment, net	4,028	4,694
Goodwill	2,333	2,333
Intangible assets, net	31	154
Right of use assets	3,406	5,806
Other long-term assets	591	529
Total assets	$ 177,781	$ 193,676
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,497	$ 1,758
Accrued liabilities	16,234	13,276
Income taxes payable	93	19
Deferred revenue	104	120
Short-term debt	2,155	90
Current lease liabilities	3,074	3,229
Total current liabilities	23,157	18,492
Deferred tax liability	114	94
Long-term lease liabilities	1,106	3,849
Long-term debt	35,089	17,234
Total liabilities	59,466	39,669
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, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 38,516,383 shares and 37,555,565 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	39	38
Additional paid-in capital	526,797	502,712
Accumulated other comprehensive income	2,640	1,575
Accumulated deficit	(411,161)	(350,318)
Total stockholders' equity	118,315	154,007
Total liabilities and stockholders' equity	$ 177,781	$ 193,676

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,	
	2023	2022
Revenue	$ 68,675	$ 53,662
Cost of goods sold	17,923	13,797
Gross profit	50,752	39,865
Operating expenses		
Research and development	18,080	15,397
Selling, general and administrative	94,607	83,105
Total operating expenses	112,687	98,502
Loss from operations	(61,935)	(58,637)
Interest income	5,568	1,529
Interest expense	(3,232)	(1,066)
Other income (expense), net	(673)	(396)
Net loss before tax	(60,272)	(58,570)
Income tax expense	571	353
Net loss	(60,843)	(58,923)
Other comprehensive income (loss)		
Currency translation adjustment	671	150
Change in unrealized gain (losses) on marketable securities	394	(287)
Total other comprehensive income (loss)	1,065	(137)
Comprehensive loss	$ (59,778)	$ (59,060)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.60)	$ (1.59)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,974,567	37,096,541

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

Pulmonx Corporation

Consolidated Statements of Stockholders' Equity

(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2021	36,931,762	$ 37	$ 482,885	$ 1,712	$ (291,395)	$ 193,239
Issuance of common stock upon vesting of restricted stock units	251,133	—	—	—	—	—
Issuance of common stock upon exercise of stock options	297,463	1	634	—	—	635
Issuance of shares pursuant to Employee Stock Purchase Plan	89,666	—	1,942	—	—	1,942
Repurchase of early exercised common stock options	(14,459)	—	—	—	—	—
Change in shares subject to repurchase	—	—	227	—	—	227
Stock-based compensation expense	—	—	17,024	—	—	17,024
Currency translation adjustment	—	—	—	150	—	150
Change in unrealized losses on marketable securities	—	—	—	(287)	—	(287)
Net loss	—	—	—	—	(58,923)	(58,923)
Balances at December 31, 2022	37,555,565	38	502,712	1,575	(350,318)	154,007
Issuance of common stock upon vesting of restricted stock units	672,180	1	(1)	—	—	—
Issuance of common stock upon exercise of stock options	137,902	—	314	—	—	314
Issuance of shares pursuant to Employee Stock Purchase Plan	150,842	—	1,184	—	—	1,184
Repurchase of early exercised common stock options	(106)	—	—	—	—	—
Change in shares subject to repurchase	—	—	144	—	—	144
Stock-based compensation expense	—	—	22,444	—	—	22,444
Currency translation adjustment	—	—	—	671	—	671
Change in unrealized gains on marketable securities	—	—	—	394	—	394
Net loss	—	—	—	—	(60,843)	(60,843)
Balances at December 31, 2023	38,516,383	$ 39	$ 526,797	$ 2,640	$ (411,161)	$ 118,315

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,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (60,843)	$ (58,923)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	22,101	16,445
(Gain) loss on disposal of fixed assets	(15)	7
Change in allowance for credit losses	(59)	54
Inventory write-downs	507	485
Depreciation and amortization expense	1,548	1,513
Amortization of debt discount and debt issuance costs	48	56
Net accretion of discounts on marketable securities	(1,025)	(204)
Non-cash lease expense	2,686	2,498
Net changes in operating assets and liabilities:		
Accounts receivable	(3,104)	(2,190)
Inventory	918	(3,638)
Prepaid expenses and other current assets	(57)	780
Other assets	(36)	(49)
Accounts payable	(345)	247
Accrued liabilities	3,176	149
Income taxes payable	68	(124)
Lease liabilities	(3,182)	(2,197)
Deferred tax liability	24	49
Deferred revenue	(20)	(41)
Net cash used in operating activities	(37,610)	(45,083)
Cash flows from investing activities		
Purchases of investments	(46,200)	(47,187)
Maturities of investments	45,000	44,280
Purchases of property and equipment	(807)	(1,318)
Net cash used in investing activities	(2,007)	(4,225)
Cash flows from financing activities		
Proceeds from borrowing under term loan	20,000	—
Repayment of credit agreement	(94)	(87)
Payments of debt issuance cost	—	(53)
Proceeds from exercise of common stock options	310	644
Proceeds from issuance of common stock under the employee stock purchase plan	1,184	1,942
Payments for the repurchase of early exercised common stock options	—	(27)
Net cash provided by financing activities	21,400	2,419
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	34	145
Net decrease in cash, cash equivalents, and restricted cash	(18,183)	(46,744)
Cash, cash equivalents, and restricted cash at beginning of year	101,967	148,711
Cash, cash equivalents, and restricted cash at end of year	$ 83,784	$ 101,967
Reconciliation of cash, cash equivalents, and restricted cash to consolidated balance sheets:		
Cash and cash equivalents	$ 83,547	$ 101,736
Restricted cash	237	231
Cash, cash equivalents, and restricted cash in consolidated balance sheets	$ 83,784	$ 101,967
Supplemental non-cash items:		

Lapse in repurchase rights of common stock	$	144	$	227
Purchases of property and equipment in accounts payable and accrued liabilities	$	109	$	425
Amount receivable from exercise of common stock options	$	3	$	—
Supplemental disclosure of cash flow information:				
Cash paid for income taxes	$	471	$	398
Cash paid for interest	$	2,984	$	847

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

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, Italy, France, Hong Kong and Japan.

Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows from operations to date and has an accumulated deficit of $411.2 million as of December 31, 2023. During the years ended December 31, 2023 and 2022, the Company used $37.6 million and $45.1 million of cash in its operating activities, respectively. As of December 31, 2023, the Company had cash, cash equivalents and marketable securities of $131.5 million. Historically, the Company's activities have been financed through the sale of equity securities, debt financing arrangements and sales of its products.

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.

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 ("U.S. 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").

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 U.S. 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, classification of short-term and long-term inventories, the recoverability of long term assets, stock-based compensation, intangible assets, goodwill, 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. 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 1 and Level 2 inputs (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, 2023 and December 31, 2022 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, and remaining maturities of less than one year, as short-term marketable securities and those with remaining maturities greater than twelve months as long-term marketable securities on the consolidated balance sheets. 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 marketable securities, which consist of debt securities, if any, are excluded from earnings and are reported as a component of 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 consolidated 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.

For marketable securities in an unrealized loss position, the Company periodically assesses its portfolio for impairment. The assessment first considers the intent or requirement to sell the marketable security. If either of these criteria are met, the amortized cost basis is written down to fair value through earnings. Upon the adoption of ASU 2016-13, *Financial Instruments – Credit Losses*, on January 1, 2023, if the criteria above are not met, the Company evaluates whether the decline resulted from credit losses or other factors by considering the extent to which fair value is less than amortized cost, any changes to the rating of the marketable security by a rating agency, and any adverse conditions specifically related to the marketable security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the marketable security is compared to the amortized cost basis of the marketable security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive loss.

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, 2023 and December 31, 2022, the Company also had cash on deposit with foreign banks of approximately $4.7 million and $4.5 million, respectively, that was not federally insured.

The Company earns revenue primarily from the sale of its products to hospitals and other customers such as distributors. Sales of Zephyr Valves and delivery catheters accounted for most of the Company's revenue for the years ended December 31, 2023 and December 31, 2022. The Company's accounts receivable are derived from revenue earned from customers. The Company performs ongoing credit evaluations of its customers' financial conditions and generally requires no collateral from its customers. As of December 31, 2023 and December 31, 2022, no customer accounted for more than 10% of accounts receivable. For the years ended December 31, 2023 and December 31, 2022, no customer accounted for more than 10% of revenue.

The Company relies on single source suppliers for the components, sub-assemblies and materials for its products. These components, sub-assemblies and materials are critical and there are no or relatively few alternative sources of supply. The Company's suppliers have generally met the Company's demand for their products and services on a timely basis in the past.

Accounts Receivable and Allowances

Accounts receivable are recorded at the amounts billed less estimated allowances for credit losses for any potential uncollectible amounts. The Company continually monitors customer payments and maintains an allowance for estimated losses resulting from a customer's inability to make required payments. The 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. Accounts receivable are written-off and charged against an allowance for credit losses when the Company has exhausted collection efforts without success. As of December 31, 2023 and December 31, 2022, accounts receivable is presented net of an allowance for credit losses of $0 and $0.1 million, 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.

The Company reviews its inventories for classification purposes. The value of inventories not expected to be realized in cash, sold or consumed during the next 12 months are classified as long-term inventory.

Internal-Use Software

The Company capitalizes certain costs in connection with obtaining or developing software for internal use. Amortization of such costs begins when the project is substantially complete and ready for its intended use.

Capitalized software development costs are classified as property and equipment, net on the consolidated balance sheets and are amortized using the straight-line method over the estimated useful life of the applicable software.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, generally between three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or useful economic life of the asset. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet, and any resulting gain or loss is reflected in operations in the period realized.

Impairment of Long-lived Assets

The Company evaluates its long-lived assets for indicators of possible impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value or discounted estimates of future cash flows. The Company has not identified any such impairment losses to date.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net tangible and identified intangible assets acquired in a business combination. Goodwill is not amortized but is evaluated at least annually for impairment or when a change in facts and circumstances indicate that the fair value of the goodwill may be below its carrying value.

The Company tests goodwill for impairment at the reporting unit level ("reporting unit"). The Company has determined that it has 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 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.

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, 2023 and 2022, 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 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. The Company does not recognize lease liabilities and ROU assets for short-term leases with terms of twelve months or less.

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 primarily from the sale of its products to hospitals and distributors 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. The Company determines revenue recognition by applying the following five steps as prescribed by ASC 606:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies performance obligations.

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer that defines each party's rights regarding the products or services to be transferred and identifies the payment terms related to these products or services, (ii) the contract has commercial substance and, (iii) the Company determines that collection of substantially all consideration for products or services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company identifies performance obligations in

contracts with customers, which may include its products and implied promises to provide free products and analysis services for patient scans. The transaction price is determined based on the amount expected to be entitled to in exchange for transferring the promised services or product to the customer. The Company is entitled to the total consideration for the products ordered by customers, net of early pay discounts, volume rebate adjustments and other transaction price adjustments. The Company's payment terms to customers generally range from 30 to 60 days. Payment terms fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Assuming all other revenue recognition criteria are met, revenue is recognized when control of the Company's products transfers to the customer. For sales where the Company's sales representative hand delivers product directly to the hospital or medical center, control transfers to the customer upon this delivery. For sales where products are shipped, control is transferred either upon shipment or delivery of the products to the customer, depending on the shipping terms and conditions. For consignment sales, control is transferred when the products are used by the customer in procedures. The Company defers revenue relating to any remaining performance obligations by the Company to the customer after delivery, such as free products and free analysis services of patient scans to determine suitability of the patients for the treatment using the Company's Zephyr Valves. As permitted under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less.

The Company accepts product returns at its discretion or if the product is defective as manufactured. Historically, the actual product returns have been immaterial to the Company's financial statements. The Company elected to treat shipping and handling costs as a fulfillment cost and include them in the cost of goods sold as incurred. In 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 $4.8 million and $6.1 million for the years ended December 31, 2023 and December 31, 2022, respectively.

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 subsidiaries in Italy and Japan is the Euro and Yen, respectively. Accordingly, asset and liability accounts of Switzerland, France, Germany, Australia, the United Kingdom, Italy, Hong Kong and Japan 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 $0.7 million and $0.2 million during the years ended December 31, 2023 and December 31, 2022, 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 $(0.8) million and $(0.4) million during the years ended December 31, 2023 and December 31, 2022, 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.

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, stock options and common stock subject to repurchase related to early exercise of stock options 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. The Company 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 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 gain or 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 income (loss) that are excluded from the reported net loss for all periods presented.

3. Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

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. The Company adopted

ASU 2016-13 as of January 1, 2023 and the adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The amendments in this ASU require disclosures, on an annual and interim basis, of significant segment expenses that are regularly provided to the chief operating decision maker (CODM), as well as the aggregate amount of other segment items included in the reported measure of segment profit or loss. This ASU requires that a public entity disclose the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss. Public entities will be required to provide all annual disclosures currently required by Topic 280 in interim periods, and entities with a single reportable segment are required to provide all the disclosures required by the amendments in the update and existing segment disclosures in Topic 280. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that this update will have on its disclosures in the consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the disclosure requirements related to the new standard.

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 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 and marketable securities.

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. The fair value of the term loan is estimated using Level 2 inputs.

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, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 25,129	$ —	$ —	$ 25,129
Total cash equivalents	25,129	—	—	25,129
Marketable securities:				
U.S. Government agency bonds	5,798	29,466	—	35,264
Commercial paper	—	12,681	—	12,681
Total marketable securities	5,798	42,147	—	47,945
Total financial assets	$ 30,927	$ 42,147	$ —	$ 73,074

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 4,647	$ —	$ —	$ 4,647
Total cash equivalents	4,647	—	—	4,647
Marketable securities:				
U.S. Government agency bonds	14,743	15,872	—	30,615
Commercial paper	—	14,711	—	14,711
Total marketable securities	14,743	30,583	—	45,326
Total financial assets	$ 19,390	$ 30,583	$ —	$ 49,973

There were no liabilities measured at fair value on a recurring and non-recurring basis as of December 31, 2023 and December 31, 2022.

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

	December 31, 2023			
	Amortized Cost	Unrealized Losses	Unrealized Gains	Fair Value
U.S. Government agency bonds	$ 35,194	$ (26)	$ 96	$ 35,264
Commercial paper	12,667	(1)	15	12,681
Total	$ 47,861	$ (27)	$ 111	$ 47,945

	December 31, 2022			
	Amortized Cost	Unrealized Losses	Unrealized Gains	Fair Value
U.S. Government agency bonds	$ 30,897	$ (282)	$ —	$ 30,615
Commercial paper	14,740	(31)	2	14,711
Total	$ 45,637	$ (313)	$ 2	$ 45,326

The following table summarizes the marketable securities with unrealized losses as of December 31, 2023 and December 31, 2022, aggregated by major security type and the length of time that individual securities have been in a continuous loss position (in thousands):

	December 31, 2023					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Government agency bonds	$ 11,888	$ (23)	$ 1,745	$ (3)	$ 13,633	$ (26)
Commercial paper	996	(1)	—	—	996	(1)
Total	$ 12,884	$ (24)	$ 1,745	$ (3)	$ 14,629	$ (27)

	December 31, 2022					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Government agency bonds	$ 19,768	$ (139)	$ 10,847	$ (143)	$ 30,615	$ (282)
Commercial paper	11,818	(31)	—	—	11,818	(31)
Total	$ 31,586	$ (170)	$ 10,847	$ (143)	$ 42,433	$ (313)

The unrealized losses for marketable securities relate to changes in interest rates. During the years ended December 31, 2023 and December 31, 2022, the Company did not consider any of its marketable securities to be other-than-temporarily impaired. No allowance for credit losses was recorded as of December 31, 2023 and December 31, 2022, and no impairment losses were recognized for the years ended December 31, 2023 and December 31, 2022.

At December 31, 2023 and December 31, 2022, accrued interest receivable on marketable securities of $0.4 million and $0.1 million was included in prepaid expenses and other current assets on the consolidated balance sheets, respectively. The Company elected to exclude accrued interest receivable from the estimation of expected credit losses on its marketable securities and reverse accrued interest receivable through interest income (expense) when

amounts are determined to be uncollectible. The Company did not write off any accrued interest receivable during the years ended December 31, 2023 and December 31, 2022.

The following table summarizes the contractual maturities of the Company's marketable securities (in thousands):

	December 31, 2023	
	Amortized Cost	Fair Value
Due within one year	$ 33,551	$ 33,555
Due in one year to five years	$ 14,310	$ 14,390
Total	$ 47,861	$ 47,945

5. Balance Sheet Components

Cash and Cash Equivalents

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

	December 31,	
	2023	2022
Cash	$ 58,418	$ 97,089
Cash equivalents:		
Money market funds	25,129	4,647
Total cash and cash equivalents	$ 83,547	$ 101,736

Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 2,924	$ 3,820
Work in process	427	386
Finished goods	15,972	15,641
Total inventory	$ 19,323	$ 19,847
Reported as:		
Inventory	$ 16,743	$ 14,564
Long-term inventory	2,580	5,283
Total inventory	$ 19,323	$ 19,847

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Prepaid expenses	$ 1,910	$ 2,044
Prepaid insurance	906	1,407
VAT and other receivable	915	602
Other current assets	504	290
Total prepaid expenses and other current assets	$ 4,235	$ 4,343

Capitalized Implementation Costs of a Hosting Arrangement

The Company has several software systems that are cloud-based hosting arrangements with service contracts. The Company accounts for costs incurred in connection with the implementation of these various software systems under ASU 2018-15, *Intangibles—Goodwill and Other—Internal Use Software (Subtopic 350–40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*. The Company expenses all costs (internal and external) that are incurred in the planning and post-implementation operation stages. As of December 31, 2023 and December 31, 2022, the Company has capitalized approximately $0.1 million and $0.5 million in implementation costs, net of amortization, respectively. The capitalized costs are amortized on a straight-line basis over the non-cancelable contract terms, which are generally three years. As of December 31, 2023, the capitalized costs of $0.1 million were included in prepaid expenses and other current assets. Amortization expense, which was included in selling, general and administrative expenses, was $0.4 million and $0.2 million for the years ended December 31, 2023 and December 31, 2022, respectively.

Property and Equipment, Net

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

	December 31,	
	2023	2022
Machinery and equipment	$ 2,271	$ 2,112
Computer equipment and software	1,872	1,773
Furniture and fixtures	264	263
Leasehold improvements	2,277	2,277
Construction in progress	2,199	1,825
Total	8,883	8,250
Less: accumulated depreciation	(4,855)	(3,556)
Property and equipment, net	$ 4,028	$ 4,694

Depreciation expense for both the years ended December 31, 2023 and December 31, 2022 was $1.4 million.

Goodwill

Goodwill was $2.3 million as of December 31, 2023 and December 31, 2022. No goodwill impairment losses have been recognized since the acquisition. There were no acquisitions or dispositions of goodwill for the years ended December 31, 2023 or December 31, 2022. The Company performed an annual test for goodwill impairment in the

fourth quarter of the fiscal years ended December 31, 2023 and December 31, 2022 and determined that goodwill was not impaired.

Intangible Assets

Intangible assets consist of the following (in thousands):

	December 31, 2023		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed technology	$ 1,658	$ (1,630)	$ 28
Trademarks	191	(188)	3
Total intangible assets	$ 1,849	$ (1,818)	$ 31

	December 31, 2022		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed technology	$ 1,658	$ (1,520)	$ 138
Trademarks	191	(175)	16
Total intangible assets	$ 1,849	$ (1,695)	$ 154

Amortization expense relating to the intangibles totaled $0.1 million during each of the years ended on December 31, 2023 and December 31, 2022.

Future amortization expense is as follows as of December 31, 2023 (in thousands):

Fiscal Year Ending December 31,	Amortization
2024	$ 31
Total amortization expense	$ 31

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued employee bonuses and commissions	$ 7,875	$ 4,973
Accrued vacation	2,400	2,113
Other accrued personnel related expenses	2,859	2,513
Accrued professional fees	1,705	2,366
Sales taxes, franchise tax and VAT	763	627
Liability for early exercise of stock options	37	145
Accrued inventory purchases	170	167
Other	425	372
Total accrued liabilities	$ 16,234	$ 13,276

6. Long Term Debt

CIBC Loan

On February 20, 2020, the Company executed a Loan and Security Agreement with Canadian Imperial Bank of Commerce ("CIBC"), which the Company subsequently amended on April 17, 2020 and December 28, 2020 (as amended, the "CIBC Agreement"). The CIBC Agreement originally provided the Company with the ability to borrow 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 draw up to an additional $8.0 million ("Tranche B") and an additional financing tranche ("Tranche C") of up to $7.0 million on or prior to February 20, 2022. Neither Tranche B nor Tranche C was drawn before the option expired.

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. 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 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 of such covenants to June 30, 2021.

In March 2021, the Company entered into an Amended and Restated Loan and Security Agreement with CIBC (as amended, the "Amended and Restated CIBC Agreement") which, among other things, extended the loan maturity date of the CIBC Loan 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 would be due beginning March 31, 2022. In connection with the Amended and Restated CIBC 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 CIBC Agreement 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 CIBC Agreement, 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.

In October 2022, the Company entered into a Third Amendment to the Amended and Restated CIBC Agreement (the "Third Amendment") with CIBC, which amended certain provisions of the CIBC Loan. The amendment provided the option to draw up to an additional $20.0 million ("Amended Tranche B") on or prior to October 31, 2023, which can be drawn in increments of at least $5.0 million. Upon request by the Company, CIBC may, in its sole discretion, make additional term loans of up to $10.0 million ("Amended Tranche C") at any time. The Third Amendment extended the maturity date of the CIBC Loan from February 20, 2025 to October 31, 2027 and provided for a new interest only period of 24 months from the signing date of the Third Amendment, with the possibility of an additional extension of such interest only period of up to 12 months, subject to satisfaction of certain conditions set forth in the Third Amendment. The Company paid a commitment fee of less than $0.1 million in connection with the Third Amendment. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In February 2023, the Company drew $20.0 million of the Amended Tranche B of the CIBC Loan. The Amended Tranche B bears interest at a floating rate equal to 1.0% above the Wall Street Journal Prime Rate and has the same repayment terms as the Tranche A.

Upon draw of the Amended Tranche B, the financial covenants in the Amended and Restated CIBC Agreement require that, when the cash and cash equivalents of the Company as defined in the Amended and Restated CIBC Agreement 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 the greater of $20.0 million and the Adjusted EBITDA loss as defined in the Amended and Restated CIBC Agreement for the six-month period ending on any date of determination. As of December 31, 2023, the Company was in compliance with all covenants contained in Amended and Restated CIBC Agreement.

The CIBC Loan bears interest at a floating rate equal to 1.0% 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 borrowings under the Amended and Restated CIBC Agreement, subject to certain conditions, including a prepayment fee equal to 2.0% of the principal amount repaid during the first year after the effective date of the Third Amendment or 1.0% of the principal amount prepaid during the second year after the effective date of the Third Amendment. As of December 31, 2023 and December 31, 2022, the CIBC Loan had an annual effective interest rate of 10.1% and 9.1% per year.

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

	December 31,	
	2023	2022
Term loan	$ 37,000	$ 17,000
Less: debt issuance costs	(152)	(127)
Term loan	$ 36,848	$ 16,873
Reported as:		
Short-term debt	$ 2,056	$ —
Long-term debt	34,792	16,873
Total term loan	$ 36,848	$ 16,873

The Company paid $0.5 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 years ended December 31, 2023 and December 31, 2022, the Company recorded interest expense related to debt discount and debt issuance costs of CIBC Loan of less than $0.1 million and $0.1 million, respectively.

Interest expense on the CIBC Loan amounted to $3.2 million and $1.1 million during the years ended December 31, 2023 and December 31, 2022, respectively.

Credit Agreement

In May 2020, Pulmonx International Sàrl, a wholly owned subsidiary of the Company, received 0.5 million Swiss Francs ($0.5 million U.S. dollar equivalent) from a COVID-19 Credit Agreement under a Swiss Federal Government program designed to mitigate the economic impact of the spread of the coronavirus. The COVID-19 Credit Agreement initially bore no interest through March 31, 2023. Beginning April 1, 2023, the COVID-19 Credit Agreement bears interest at a rate of 1.5% per year, payable at the end of each calendar quarter. The loan principal is being repaid in twelve equal installments, paid semi-annually, which began in March of 2022. Interest expense was immaterial during the year ended December 31, 2023. Pulmonx International Sàrl repaid $0.1 million and $0.1 million to the lender during the years ended December 31, 2023 and December 31, 2022, respectively.

Contractual Maturities of Financing Obligations

As of December 31, 2023, the aggregate future payments under the CIBC Loan and Credit Agreement (including interest payments) are as follows (in thousands):

Fiscal Year Ending December 31,		Amount
2024	$	5,666
2025		15,217
2026		14,043
2027		10,823
Total	$	45,749
Less: unamortized debt discount		(152)
Less: interest		(8,353)
Term loan and credit agreement	$	37,244

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 $0.1 million as of December 31, 2023, which is expected to be recognized as revenue in fiscal year 2024. The deferred revenue as of December 31, 2022 was $0.1 million, which was recognized as revenue during the year ended December 31, 2023. The deferred revenue as of December 31, 2021 was $0.2 million, which was recognized as revenue during the year ended December 31, 2022.

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.

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 "Sublease Agreement"). The Sublease 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 the Sublease Agreement to include additional facility space in Redwood City, California for a four-year term (the "First Amendment to Sublease Agreement"). The First Amendment to Sublease Agreement was accounted as a separate sublease agreement. The First Amendment to 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 First Amendment to 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 First Amendment to Sublease Agreement 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. In April 2023, the Company entered into a Second Amendment to Sublease Agreement (the "Second Amendment to Sublease Agreement") to remove the early termination clause and extend the lease term by four months to expire contemporaneously with the expiration date as defined in Sublease Agreement. The amendment was accounted for as a modification that resulted in additional right of use assets in exchange for lease liabilities of $0.2 million.

As of December 31, 2023, the Company has leases on 14 vehicles with an average lease term of 3.0 years.

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

	Years Ended December 31,	
	2023	2022
Operating lease cost	$ 2,884	$ 2,893
Short-term lease cost	38	35
Variable lease cost	652	599
Total lease cost	$ 3,574	$ 3,527

The following table summarizes a maturity analysis of the Company's lease liabilities showing the aggregate lease payments as of December 31, 2023 (in thousands):

Fiscal Year Ending December 31,	Amount
2024	$ 3,219
2025	1,098
2026	30
Total minimum lease payments	4,347
Less: Amount of lease payments representing interest	167
Present value of future minimum lease payments	$ 4,180
Less: Current lease liabilities	3,074
Long-term lease liabilities	$ 1,106

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

	December 31,	
	2023	2022
Right of use asset	$ 3,406	$ 5,806
Weighted average remaining lease term (years)	1.35	2.08
Weighted average discount rate	6.7 %	6.0 %

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

	Years Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities included in cash flows used in operating activities	$ 3,563	$ 2,701
Right-of-use assets obtained in exchange for lease liabilities	$ 284	$ 229

Service Agreement

In April 2022, the Company entered into an agreement with a service provider, which requires total minimum purchases of $0.6 million, $0.4 million, and $0.4 million over a three-year period. From inception of the agreement through December 31, 2023, the Company recorded $0.9 million of expense for services related to this agreement in cost of goods sold.

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.

In December 2022, the Company received a civil investigative demand ("CID") from the U.S. Department of Justice, Civil Division in connection with an investigation under the Anti-Kickback Statute and False Claims Act (the "Investigation"). The CID requests information and documents regarding the Company's relationships with certain health care providers, medical practices, and hospitals in connection with the sales and marketing of the Zephyr Valves and related products and services. The Company is fully cooperating with the Investigation. The Company is unable to express a view at this time regarding the ultimate outcome of the Investigation or estimate an amount or range of reasonably possible loss. Depending on the outcome of the Investigation, there could be a material impact on the Company's business, results of operations and financial condition.

9. Income Taxes

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

	Years Ended December 31,	
	2023	2022
Domestic	$ (60,503)	$ (59,361)
Foreign	231	791
Total loss before provision for taxes	$ (60,272)	$ (58,570)

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

	Years Ended December 31,	
	2023	2022
Current:		
Federal	$ —	$ —
State	62	66
Foreign	483	232
Total current expense	$ 545	$ 298
Deferred:		
Federal	$ 7	$ 32
State	10	14
Foreign	9	9
Total deferred expense	26	55
Total income tax expense	$ 571	$ 353

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

	Years Ended December 31,	
	2023	2022
Federal statutory rate	21.0 %	21.0 %
State taxes, net of federal benefit	(0.1)%	(0.1)%
Foreign earnings at different rates	(0.5)%	(0.1)%
Tax credits	(0.9)%	1.8 %
Permanent differences	(4.6)%	(4.6)%
Prior year true-up	0.6 %	(0.8)%
Change in valuation allowance	(16.4)%	(17.8)%
Effective tax rate	(0.9)%	(0.6)%

Deferred income taxes arise from temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax reporting purposes, as well as operating losses and tax credit carryforwards. Significant components of the Company's deferred tax assets and liabilities for federal and state income taxes are as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 57,420	$ 50,316
Tax credit carryforwards	6,493	7,169
Accruals and reserves	2,287	1,900
Depreciation	243	183
Intangible assets	4,049	4,394
Right of use liability	920	1,443
Capitalized research costs	5,749	2,838
Other	3,371	1,739
Gross deferred tax assets	80,532	69,982
Less: valuation allowance	(79,362)	(68,427)
Deferred tax assets	$ 1,170	$ 1,555
Deferred tax liabilities:		
Right of use asset	$ (739)	$ (1,147)
Goodwill	(545)	(502)
Net deferred tax liabilities	$ (114)	$ (94)

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 $79.4 million as of December 31, 2023. The valuation allowance increased by $10.9 million and $11.9 million for the years ended December 31, 2023 and December 31, 2022, respectively.

As of December 31, 2023, the Company had a total net operating loss carryforwards for federal income tax purposes of approximately $245.8 million. If not utilized, these net federal operating loss carryforwards will begin to expire in 2024. The Company also had a state net operating loss carryforward of approximately $155.4 million which will begin to expire in 2024.

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, 2023, the Company had $173.9 million of 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 $3.6 million and $5.1 million, respectively. The federal tax R&D credit carryforwards will expire beginning in the year 2030 while the state tax 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 section 382 study for which the Company wrote off deferred tax assets for net operating losses 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 net operating losses or credits will expire unused due to the 2020 annual limitation. The Company completed another section 382 study for the year ended December 31, 2022 for which the Company had no change in ownership. Additionally, based on the Company's analysis, no further material net operating losses or credits have expired unused due to the section 382 limitations as of December 31, 2023.

Annually, the Company determines whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities in considering whether any tax benefit can be recorded in the consolidated financial statements. As of December 31, 2023, the Company had unrecognized tax benefits of approximately $8.7 million, none of which will affect the effective tax rate if recognized. It is unlikely that the amount of liability for unrecognized tax benefits will significantly change over the next 12 months.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits (in thousands):

Balance at December 31, 2021	$	8,489
Additions for tax positions related to prior year		106
Decreases for tax positions related to prior year		(153)
Additions for tax positions related to current year		200
Balance at December 31, 2022	$	8,642
Additions for tax positions related to prior year		144
Decreases for tax positions related to prior year		(162)
Additions for tax positions related to current year		38
Balance at December 31, 2023	$	8,662

It is the Company's policy to include penalties and interest expense related to income taxes as a component of other income (expense), net and interest expense, respectively, as necessary.

The Company's major tax jurisdictions are the United States and California, and 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 losses or R&D Credits. The Company does not have any tax audits or other issues pending.

As currently enacted, the Tax Cuts and Jobs Act (the "Tax Act") requires taxpayers to capitalize research and development expenses with amortization periods over five and fifteen years, which is expected to decrease the amount of the Company's generated net operating losses during the year.

10. Stockholders' Equity

Common Stock

As of December 31, 2023 and December 31, 2022, the Company's certificate of incorporation authorized the Company to issue up to 200,000,000 shares of common stock. Common stockholders are entitled to dividends as and when declared by the Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

Shares Reserved for Future Issuance

The Company has reserved shares of common stock for future issuances as follows:

	December 31,	
	2023	2022
Common stock options issued and outstanding	3,142,981	2,495,528
Common stock restricted stock units issued and outstanding	2,244,903	998,473
Common stock available for future grants	2,541,438	3,765,706
Common stock available for ESPP	1,436,823	1,212,109
Total	9,366,145	8,471,816

Stock Option Plan

As of December 31, 2023, the Company reserved 14,249,394 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 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, 2023 and December 31, 2022, no shares of common stock remain available for issuance to officers, directors, employees and consultants pursuant to the 2000 Stock Plan. In January 2024, the number of shares of common stock available for issuance under the 2020 Equity Incentive Plan was increased by 1,540,655 shares as a result of the automatic increase provision in the 2020 Equity Incentive 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. Options vest ranging from immediately upon grant to a rate of 25% per annum over four years from the grant date. Options expire 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, 2021	2,145,131	$ 13.44
Options granted	765,900	24.09
Options exercised	(297,463)	2.13
Options canceled	(118,040)	28.30
Balance, December 31, 2022	2,495,528	$ 17.35
Options granted	835,400	11.48
Options exercised	(137,902)	2.27
Options canceled	(50,045)	20.62
Balance, December 31, 2023	3,142,981	$ 16.40

The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and December 31, 2022 was $1.3 million and $4.6 million, respectively.

The aggregate intrinsic value of options outstanding as of December 31, 2023 and December 31, 2022 was $11.1 million and $6.9 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, 2023 and December 31, 2022.

	December 31, 2023		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Life (in Years)
Options vested	1,751,674	$ 15.34	6.70
Options vested and expected to vest	3,142,981	$ 16.40	7.47

The aggregate intrinsic value of options exercisable as of December 31, 2023 and December 31, 2022 was $8.6 million and $4.1 million, respectively.

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 granted under these plans 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 years ended December 31, 2023 and December 31, 2022, the Company repurchased 106 and 14,459 shares of common stock for less than $0.1 million and less than $0.1 million, respectively. As of December 31, 2023 and December 31, 2022, 109 and 77,782 shares were subject to repurchase, with an aggregate exercise price of less than $0.1 million and $0.1 million, respectively, and were recorded in accrued liabilities on the consolidated balance sheets.

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, December 31, 2021	442,428	$ 42.36
Granted	937,400	23.63
Vested	(251,133)	35.09
Canceled	(130,222)	33.85
Unvested, December 31, 2022	998,473	27.72
Granted	2,042,593	11.48
Vested	(672,180)	19.93
Canceled	(123,983)	19.29
Unvested, December 31, 2023	2,244,903	$ 15.74

The fair value as of the respective vesting dates of restricted stock units that vested during the years ended December 31, 2023 and December 31, 2022 was $7.5 million and $3.9 million, respectively. The aggregate intrinsic

value of restricted stock units outstanding as of December 31, 2023 and December 31, 2022 was $28.6 million and $8.4 million, respectively.

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, 2023 and December 31, 2022 was $7.77 and $10.74 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, 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,	
	2023	2022
Weighted average expected term (in years)	6.0	6.0 - 6.1
Volatility	73.4%	44.5% - 44.8%
Risk-free interest rate	4.2%	1.6% - 3.6%
Dividend yield	—	—

Expected Term

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

Volatility

The expected stock price volatility assumptions for the Company's stock options for the years ended December 31, 2023 and December 31, 2022 were determined using the Company's historical volatility and the historical volatilities of industry peers, referred to as "guideline" companies, as the Company had limited trading history for the Company's common stock. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

The expected stock price volatility assumptions for the purchase rights under the employee share purchase plan for the years ended December 31, 2023 and December 31, 2022 were determined using the historical volatility of the Company's common stock.

Risk-Free Rate

The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

Dividend Yield

The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

Fair Value of Common Stock

The fair value of the Company's common stock is determined based on its closing market price on the date of grant.

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 Company entered into a new offering period beginning August 16, 2023 and ending February 15, 2024.

The Company issued 150,842 and 89,666 shares under the ESPP for the years ended December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023, there were 1,436,823 shares authorized for future purchase under the ESPP. In January 2024, the number of shares of common stock available for issuance under the ESPP was increased by 385,164 shares as a result of the automatic increase provision in the ESPP.

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

	Years Ended December 31,	
	2023	2022
Weighted average expected term (in years)	0.5	0.5
Volatility	43.4% - 55.6%	37.8% - 42.8%
Risk-free interest rate	5.0% - 5.5%	0.7% - 3.1%
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,	
	2023	2022
Cost of goods sold	$ 1,320	$ 686
Research and development	2,821	2,190
Selling, general and administrative	17,960	13,569
Total	$ 22,101	$ 16,445

The above stock-based compensation expense related to the following equity-based awards (in thousands):

	Years Ended December 31,	
	2023	2022
Stock options and restricted stock units	$ 21,675	$ 15,807
ESPP	426	638
Total	$ 22,101	$ 16,445

Stock-based compensation of $1.6 million and $1.2 million was capitalized into inventory for the years ended December 31, 2023 and 2022, respectively. Stock-based compensation capitalized in prior periods of $1.3 million and $0.7 million was recognized as cost of sales in the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, there was $43.7 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 2.5 years. The total grant date fair value of shares vested during the years ended December 31, 2023 and December 31, 2022 was $21.7 million and $15.5 million, respectively.

As of December 31, 2023, 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.

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,	
	2023	2022
Numerator		
Net loss attributable to common stockholders	$ (60,843)	$ (58,923)
Denominator		
Weighted-average common stock outstanding	37,998,509	37,248,292
Less: weighted-average common shares subject to repurchase	(23,942)	(151,751)
Weighted-average common shares used to compute basic and diluted net loss per share	37,974,567	37,096,541
Net loss per share attributable to common stockholders, basic and diluted	$ (1.60)	$ (1.59)

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,	
	2023	2022
Options to purchase common stock	3,142,981	2,495,528
Unvested restricted stock units	2,244,903	998,473
Unvested early exercised common stock options	109	77,782
Shares committed under ESPP	55,714	28,141
Total Shares	5,443,707	3,599,924

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):

	Years Ended December 31,	
	2023	2022
United States	$ 45,917	$ 32,487
Europe, Middle-East and Africa ("EMEA")	19,336	18,154
Asia Pacific	3,023	2,866
Other International	399	155
Total	$ 68,675	$ 53,662

Revenue from Germany represented 8% and 11% of total revenue for the years ended December 31, 2023 and 2022, 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,	
	2023	2022
United States	$ 3,962	$ 4,634
Europe, Middle-East and Africa	54	58
Asia Pacific	12	2
Total	$ 4,028	$ 4,694

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.

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 Interim 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 Interim 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 Interim Chief Financial Officer, has concluded that our disclosure controls and procedures were effective as of December 31, 2023.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Interim 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 Interim 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, 2023 based on the criteria set forth in Internal

Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2023.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Insider Trading Arrangements

During the three months ended December 31, 2023, none of our directors or officers adopted or terminated (i) any contract, instruction or written plan for the purchase or sale of securities of the Company intended to satisfy the affirmative defense conditions of Rule 10b5–1(c) (a “Rule 10b5-1 trading arrangement”) or (ii) any "non-Rule 10b5-1 trading arrangement” as defined in Item 408(c) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 Proxy Statement is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information regarding our independent auditor fees and serves in the section captioned “Proposal No. 2—Ratification of Selection of Independent Registered Public Accounting Firm—Principal Accounting Fees and Services” of the 2024 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 2024 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

Exhibit Number	Description of Document	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Pulmonx Corporation.	8-K	001-39562	3.1	October 5, 2020	
3.2	Amended and Restated Bylaws of Pulmonx Corporation.	S-1/A	333-248635	3.4	September 24, 2020	
4.1	Form of common stock certificate of Pulmonx Corporation.	S-1/A	333-248635	4.1	September 24, 2020	
4.2	Description of common stock of Pulmonx Corporation.	10-K	001-39562	4.3	March 15, 2021	
10.1+	Amended and Restated 2010 Stock Plan.	S-8	333-249187	99.1	October 1, 2020	
10.2+	Forms of Notice of Stock Option Grant, Option Agreement, and Exercise Notice under Amended and Restated 2010 Stock Plan.	S-8	333-249187	99.2	October 1, 2020	
10.3+	Amended and Restated 2020 Stock Plan.	S-8	333-249187	99.3	October 1, 2020	
10.4+	Forms of Notice of Stock Option Grant, Option Agreement, and Exercise Notice under Amended and Restated 2020 Stock Plan.	S-8	333-249187	99.4	October 1, 2020	
10.5+	2020 Equity Incentive Plan.	S-8	333-249187	99.5	October 1, 2020	

10.6+	Forms of Option Agreement and Notice of Stock Option Grant under 2020 Equity Incentive Plan.	S-8	333-249187	99.6	October 1, 2020
10.7+	Form of Restricted Stock Unit Award Agreement under 2020 Equity Incentive Plan.	S-8	333-249187	99.7	October 1, 2020
10.8+	2020 Employee Stock Purchase Plan.	S-8	333-249187	99.8	October 1, 2020
10.9	Form of Indemnification Agreement by and between Pulmonx Corporation and each of its directors and executive officers.	S-1/A	333-248635	10.9	September 24, 2020
10.10+	Executive Employment Agreement, by and between Pulmonx Corporation and Glendon E. French, dated December 10, 2014.	S-1/A	333-248635	10.10	September 24, 2020
10.11+	Offer Letter Agreement, by and between Pulmonx Corporation and Geoffrey Beran Rose, dated December 11, 2014.	S-1/A	333-248635	10.11	September 24, 2020
10.12+	Offer Letter Agreement, by and between Pulmonx Corporation and Derrick Sung, Ph.D., dated March 12, 2019.	S-1/A	333-248635	10.12	September 24, 2020
10.13+	Offer Letter Agreement, by and between Pulmonx Corporation and David Lehman, dated September 15, 2020	10-K	001-39562	10.13	March 15, 2021
10.14	Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated September 4, 2009.	S-1/A	333-248635	10.18	September 24, 2020
10.15	First Amendment to Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated October 3, 2014.	S-1/A	333-248635	10.19	September 24, 2020
10.16	Second Amendment to Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated November 7, 2019.	S-1/A	333-248635	10.20	September 24, 2020
10.17	Sublease, by and between Pulmonx Corporation and Genomic Health, Inc., dated April 8, 2020.	S-1/A	333-248635	10.21	September 24, 2020
10.18	First Amendment to Sublease Agreement, by and between Pulmonx Corporation and Genomic Health, Inc., dated September 10, 2020.	S-1/A	333-248635	10.22	September 24, 2020
10.19	Intellectual Property Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank of Commerce, dated February 20, 2020.	S-1/A	333-248635	10.25	September 24, 2020

10.20	Note Purchase Agreement and Form of 2020 Note, by and between Pulmonx Corporation and the purchasers of the 2020 Notes, dated April 17, 2020.	S-1/A	333-248635	10.26	September 24, 2020	
10.21+	Pulmonx Corporation Severance and Change in Control Plan and related participation agreement.	S-1/A	333-248635	10.27	September 28, 2020	
10.22	Second Amendment and Waiver to Loan and Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank of Commerce, dated December 28, 2020.	10-Q	001-39562	10.1	May 12, 2021	
10.23	Amended and Restated Loan and Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank Commerce, dated March 29, 2021.	10-Q	001-39562	10.2	May 12, 2021	
10.24	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.	10-Q	001-39562	10.1	August 10, 2021	
10.25	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.	10-Q	001-39562	10.1	November 9, 2021	
10.26	Third Amendment to Amended and Restated Loan and Security Agreement, by and between Pulmonx Corporation and Canadian Imperial Bank of Commerce, dated October 31, 2022.	10-K	001-39562	10.27	March 1, 2023	
10.27+	Pulmonx Corporation Amended and Restated Non-Employee Director Compensation Policy.	10-Q	001-39562	10.1	August 4, 2023	
10.28	Second Amendment to Sublease, by and between Pulmonx Corporation and Genomic Health, Inc., dated April 18, 2023.	10-Q	001-39562	10.2	August 4, 2023	
10.29+	Consulting Agreement, dated November 1, 2023, by and between Pulmonx Corporation and Derrick Sung.	10-Q	001-39562	10.1	November 3, 2023	
10.30+	Pulmonx Corporation Amended and Restated Non-Employee Director Compensation Policy.					X
21.1	List of Subsidiaries of Registrant.	10-K	001-39562	21.1	March 1, 2023	
23.1	Consent of BDO USA, P.C., independent registered public accounting firm.					X

24.1	Power of Attorney (included on signature page hereto).	X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
31.2	Certification of Interim Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
32.1*	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.	X
32.2*	Certification of Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
97.1	Pulmonx Corporation Incentive Compensation Recoupment Policy.	X
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 27th day of February, 2024.

PULMONX CORPORATION

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

By: /s/ John McKune
John McKune
Interim 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 John McKune, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to 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 or she 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:

Signature	Title	Date
/s/ Glendon E. French Glendon E. French	President, Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2024
/s/ John McKune John McKune	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2024
/s/ Thomas W. Burns Thomas W. Burns	Director	February 27, 2024
/s/ Richard Ferrari Richard Ferrari	Director	February 27, 2024
/s/ Daniel P. Florin Daniel P. Florin	Director	February 27, 2024
/s/ Georgia Garinois-Melenikiotou Georgia Garinois-Melenikiotou	Director	February 27, 2024
/s/ Alissa Hsu Lynch Alissa Hsu Lynch	Director	February 27, 2024
/s/ Dana G. Mead, Jr. Dana G. Mead, Jr.	Director	February 27, 2024
/s/ Tiffany Sullivan Tiffany Sullivan	Director	February 27, 2024

Exhibit 10.30

PULMONX CORPORATION

AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Approved by the Compensation Committee of the Board of Directors
December 13, 2023

ELIGIBILITY

Each member of the board of directors (the "***Board***") of Pulmonx Corporation (the "***Company***") who is not a full- or part- time officer or employee of the Company or any of its subsidiaries (a "***Non-Employee Director***") is eligible to receive compensation under this Non-Employee Director Compensation Policy (this "***Policy***") during the period of the Non-Employee Director's service as a member of the Board. A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

EQUITY COMPENSATION

Equity awards will be granted under the Company's 2020 Equity Incentive Plan, as amended from time to time, or any successor equity incentive plan (the "***Plan***"). Unless otherwise defined herein, capitalized terms used in this Policy have the meaning given to such terms in the Plan. All stock options granted under this Policy will be Non-statutory Stock Options, with a term of ten years from the date of grant (subject to earlier termination upon a termination of the Non-Employee Director's Continuous Service) and an exercise price per share equal to the closing price of a share of the Company's Common Stock on the date of grant. Grants of equity hereunder will be made on the applicable Quarterly Granting Date.

- *Certain Definitions*. As used in this Policy:
  - "***Calculation Stock Price***" means the average closing price of the Company's Common Stock, as calculated in accordance with the Company's then current calculation methodology, applicable to the Company Quarterly Granting Date when an Initial Equity Grant or an Annual Equity Grant (as defined below) is to be made.
  - "***Fair Market Value:***"

    For **stock options** granted hereunder will be based on the Black-Scholes pricing method and will use the Calculation Stock Price.

    For Restricted Stock Units ("***RSUs*****")** granted hereunder will be based on the value of such RSU grant divided by the Calculation Stock Price.
  - "***Quarterly Granting Date***" means the four annual dates on which the Company grants equity awards.
- *Initial Equity Grant*. Each Non-Employee Director who is elected or appointed to the Board for the first time after the effective date of this Policy will be granted, at the discretion of the Board of Directors, either or a combination of (a) an option to purchase shares of Common Stock (the

"***Initial Stock Option Grant***") or (b) Company RSUs (the "***Initial RSU Grant***") with an aggregate Fair Market Value of an amount equal to the pro-rata value of the Annual Equity Grant (as defined below) granted to Directors at the immediately previous Annual Meeting of Stockholders, based on the month in which the new Non-Employee Director commences service on the Board (the Initial Stock Option Grant and the Initial RSU Grant shall be referred to alternatively or collectively herein as the "***Initial Equity Grant***"). Such Initial Equity Grant will be made on the Company Quarterly Granting Date immediately following the date of his or her initial election or appointment to the Board.

- *Initial Stock Option Grant*. The shares subject to the Initial Stock Option Grant will vest in equal monthly amounts on the same, pro-rated, vesting schedule as the Annual Equity Grant on the one-month anniversary of the date of grant and each month thereafter on the same day of the month as the grant date, subject to the Non-Employee Director's Continuous Service through each vesting date, such that the Initial Stock Option Grant will be fully vested on the date of the next Annual Meeting of Stockholders or the same day of the month as the Initial Stock Option grant date in the month when the Annual Meeting of Stockholders is held, whichever is earlier.
- *Initial RSU Grant*. One hundred percent (100%) of the RSUs subject to the Initial RSU Grant will vest on the date of the next Annual Meeting of Stockholders or the same day of the month as the Initial RSU grant date in the month when the Annual Meeting of Stockholders is held, whichever is earlier, or if such date is not a business day, then on the next business day, subject to the Non-Employee Director's Continuous Service through each vesting date.

- *Annual Equity Grant*. With respect to each annual meeting following the applicable Non-Employee Director's Initial Equity Grant, each person who continues to serve as a Non-Employee Director following such annual meeting will be granted, at the discretion of the Board of Directors, either or a combination of (a) an option to purchase shares of Common Stock (the "***Annual Stock Option Grant***") or (b) Company RSUs (the "***Annual RSU Grant***") with an aggregate Fair Market Value of $125,000 on the Company Quarterly Granting Date immediately following the date of the Company's Annual Meeting of Stockholders (the Annual Stock Option Grant and the Annual RSU Grant shall be referred to alternatively or collectively herein as the "***Annual Equity Grant***").
  - *Annual Stock Option Grant*. One-twelfth ($1/12^{th}$) of the shares subject to each Annual Stock Option Grant will vest on the one-month anniversary of the date of grant and each month thereafter on the same day of the month as the grant date, provided that the twelfth vesting date of each such grant will occur no later than the date of the Annual Meeting for the year subsequent to the date such Annual Stock Option Grant is made, subject to the Non-Employee Director's Continuous Service through each vesting date.
  - *Annual RSU Grant.* In the case of the Annual RSU Grant, all of the RSUs subject to the Annual RSU Grant will vest on the earlier of (i) the one-year anniversary of the date of grant on the same day of the month as the grant date, or if such date is not a business day, then on the next business day, or (ii) the date of the Annual Meeting for the year subsequent to the date such Annual RSU Grant is made, subject to the Non-Employee Director's Continuous Service through such vesting date.

- *Change in Control.* Notwithstanding the above, for each Non-Employee Director who remains in Continuous Service with the Company until immediately prior to the closing of a Change in Control, any unvested shares subject to his or her then-outstanding equity awards that were granted pursuant to this Policy will become fully vested and exercisable immediately prior to the closing of such Change in Control.

CASH COMPENSATION

Each Non-Employee Director will receive an annual Board service retainer of $45,000 in cash for serving on the Board. A Non-Employee Director who serves as a non-executive chairperson of the Board will receive an additional annual cash service retainer of $40,000 for serving in that role.

The chairperson and other members of the three standing committees of the Board will be entitled to the following additional annual cash retainers:

Board Committee	Chairperson	Other Member
Audit Committee	$ 20,000	$10,000
Compensation Committee	$ 15,000	$7,500
Nominating and Corporate Governance Committee	$ 10,000	$5,000

All annual cash retainers will be payable in equal quarterly installments, in arrears, no later than 30 days following the end of each quarter in which the Board service occurs, prorated for any partial quarter of service (based on the number of days served in the applicable position divided by the total number of days in the quarter). All annual cash retainers will be vested upon payment.

The Company will also reimburse each Non-Employee Director for all ordinary, necessary and reasonable out-of-pocket travel expenses incurred by the Non-Employee Director in attending in person and participating in meetings of the Board or any committee thereof and any meetings of the stockholders of the Company, provided the Non-Employee Director timely submits to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

AMENDMENTS

This Policy may be amended by the Board or the Compensation Committee of the Board at any time.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-271769, 333-264825, 333-256140 and 333-249187) of Pulmonx Corporation of our report dated February 27, 2024, relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, P.C.

San Francisco, California

February 27, 2024

Exhibit 31.1

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: February 27, 2024

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

Exhibit 31.2

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, John McKune, 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: February 27, 2024

By: /s/ John McKune

John McKune

Interim Chief Financial Officer

Exhibit 32.1

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 fiscal year ended December 31, 2023 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 results of operations of the Company.

Date: February 27, 2024

By: /s/ Glendon E. French

Glendon E. French

President, Chief Executive Officer and Director

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulmonx Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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 fiscal year ended December 31, 2023 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 results of operations of the Company.

Date: February 27, 2024

By: /s/ John McKune
John McKune
Interim Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulmonx Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 97.1

PULMONX CORPORATION

INCENTIVE COMPENSATION RECOUPMENT POLICY

APPROVED BY THE COMPENSATION COMMITTEE
SEPTEMBER 27, 2023

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of Pulmonx Corporation, a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive

Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

PULMONX CORPORATION

INCENTIVE COMPENSATION RECOUPMENT POLICY

FORM OF EXECUTIVE ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Pulmonx Corporation Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Pulmonx Corporation (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

Name: __

Title: __

Date: __