

## Risk Factors Comparison 2025-02-25 to 2024-02-27 Form: 10-K

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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-products**, 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 **;**
- **If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, interruptions to our operations such as to our LungTraX Platform services or our clinical trials, claims that we breached our data protection obligations, harm to our reputation, business operations, and financial condition, as well as a loss of customers or sales** ;

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 **or certification** 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 **involved in a party to** intellectual property litigation **, infringement claims,** 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 **LungTraX StratX Lung Analysis Platform (“ which is called the StratX Platform ” in international markets**), 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~~ **from** the U. S. Food and Drug Administration (“ FDA ”). The Zephyr Valve is now commercially available in **numerous more than 25** countries **globally**, 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 ~~400~~ **150** 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 **also manufacture the AeriSeal System, which is a synthetic polymer foam designed to occlude, or close, collateral air channels in a target lung lobe and convert the target lung lobe to having little to no collateral ventilation (CV-). The AeriSeal System has received a “ Breakthrough Device ” designation by the FDA and a Certificate of Conformity (“ CE Mark ”) in Europe. The AeriSeal System is not approved by the FDA or approved for commercial sale in the United States. We are currently conducting a global clinical trial called CONVERT II to support a PMA application for the AeriSeal System.** 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. **For 2024, we generated 96 % of our revenue from markets where we sell directly.** We generated revenue of \$ ~~68.83~~ **78** million, with a gross margin of ~~73.74~~ **90** % and a net loss of \$ ~~60.56~~ **8.4** million, for the year ended December 31, ~~2023~~ **2024** compared to revenue of \$ ~~53.68~~ **7** million, with a gross margin of ~~74.73~~ **3.9** % and a net loss of \$ ~~58.60~~ **9.8** million, for the year ended December 31, ~~2022~~ **2023**. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of \$ ~~411.467~~ **2.6** 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 LungTraX~~ Platform, while used to identify patients eligible for treatment with Zephyr Valves, ~~does not independently generate revenue~~ **has** 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~~ **fourth** leading cause of death worldwide, causing 3. ~~23~~ **5** million deaths in ~~2019~~ **2021**, **approximately 5 % of all global deaths**. 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 LungTraX~~ 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 25-40,000 patients treated globally with Zephyr Valves; • High procedural success driven by innovative and effective patient assessment tools; and • Minimally invasive procedure typically lasting **approximately one 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-LungTraX** 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-LungTraX** 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-LungTraX** 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. 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. The **StratX LungTraX** Platform is a cloud-based quantitative CT (“QCT”) analysis service that provides physicians with **multiple products – LungTraX Connect, to improve workup efficiency, LungTraX Detect, to enable patient identification and** an easy-to-read **StratX Lung** 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 LungTraX Connect Software enables a streamlined, efficient, and collaborative workup process including CD-less uploading of CT scan of the images, a collaborative patient management tool**’s chest according to the StratX parameters, **and a** 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 list, **which includes** 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”). **LungTraX Detect allows for seamless picture archiving and communication system (“PACS”) integration and a rule-based screening of patients from that data with emphysema using CT scans within the hospital PACS. The system continues to support the legacy process of manually uploading CT scans. After the CT scan is uploaded to a third-party cloud service provider, in it is analyzed using validated algorithms. The LungTraX 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 the their patients using the simple-to-read StratX Lung Report. In order to make the LungTraX Platform available to** physicians **have, inadvertently, not removed the PHI themselves we contract with a third-party cloud service provider**. 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 **LungTraX Platform** 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 LungTraX** accounts and cases and monitor this CT scan upload and analysis process to ensure quality control. 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 benefited~~ **benefit** 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 over 650** 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~~, **and the results were published in the American Journal of Respiratory and Critical Care Medicine in 2018**. In addition, over **100-150** scientific articles have been published on the clinical ~~benefits~~ **benefits use** 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 (FEV1) assessments **and the findings demonstrating long- term durability (out to at least 5 years) were presented at the 2024 European Respiratory Society Congress in Vienna**. We have also established ~~a three separate~~ **patient registry registries** to collect additional **real- world** data on the safety and effectiveness (FEV1) of the Zephyr Valve in the United States, **France and Japan**. ~~Results from the French~~ **We have established a similar registry in France demonstrating clinically meaningful benefits of the Zephyr valves with and an Japan-acceptable safety profile were also presented at the 2024 European Respiratory Society Congress in Vienna**. 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  $\geq$  350mL Lung Function (FEV1 %)  $\uparrow$  MCID  $\geq$  10 %- 15 % Exercise Capacity (6MWD)  $\uparrow$  MCID  $\geq$  26 m Quality of Life (SGRQ)  $\uparrow$  MCID  $\geq$  4 pts LIBERATE n = 19012 Mo84 % 18. 0 % p < 0. 00139 mp = 0. 002- 7. 1 pts p = 0. 004 TRANSFORM n = 976 Mo90 % 29. 3 % p < 0. 00179 mp < 0. 001- 6. 5 pts p = 0. 031 IMPACT n = 936 Mo89 % 16. 3 % p < 0. 001 \* \* 28 mp = 0. 016 \* \*- 7. 5 pts p < 0. 001 \* \* STELVION n = 686 Mo88 % 17. 8 % ~~P- p~~ = 0. 00174 mp < 0. 001 ~~4~~- 14. 7 pts \* ~~P- p~~ < 0. 001

$\uparrow$  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 in~~ the lung and is believed to be a direct result of rapid shifts in ~~air the lobar volume volumes~~ in the chest as the target lobe deflates and the neighboring lobe expands. In clinical trials, **in the incidence rate of pneumothoraces pneumothorax occurred in 18-34 % of patients treated with the Zephyr Valve, is between 18 % and in 34 %**. In the LIBERATE Study, 17 % of the pneumothorax events required no intervention and resolved on their own. **While Patients patients with a pneumothorax had a longer hospital stay of approximately a week versus the 3- night stay for patients who did not have a had their pneumothoraces pneumothorax, following the successfully-- successful treated resolution of the pneumothorax they had comparable outcomes to those who did not experience a pneumothorax, other than that their hospital stays were extended by approximately a week**. **Recent publications have reported improved survival in patients with severe hyperinflation undergoing bronchoscopic lung volume reduction (BLVR) with valves compared to the a matched population not undergoing BLVR. Based on three-- the nights strength of the clinical evidence, the Zephyr valves are included as a standard- of- care treatment option in global guidelines (Global Initiative for patients without pneumothoraces Chronic Obstructive Lung Disease; GOLD) with Evidence Level " A " . Our 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 **educate 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 **educate 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 **generally** 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 Valves~~, 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 **80-75 %** of the potential Zephyr Valve patient population are Medicare ~~beneficiaries, 5 %~~ 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~~ **or other government programs**. 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 **clinical data and global treatment recommendations for the management of COPD and emphysema** 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. **We expect that continued patient demand coupled with successful appeals of any initially denied prior authorization requests will lead to more positive coverage policies.** 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~~ **Switzerland**, 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 **System** assessment, valve deliverability and reduce procedure time and the use of **the AeriSeal System** for addressing the needs of severe emphysema patients who are not eligible for Zephyr Valves due to collateral ventilation. **The AeriSeal System is a synthetic polymer foam designed polymerizing sealant that can be delivered via a bronchoscope to occlude, or close, collateral air channels in a targeted-- target region of the lung lobe and convert to reduce volume in the treated area target lung lobe to having little to no collateral ventilation (CV-).** We believe that **the AeriSeal System** 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 **System** 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. **In December 2020, the AeriSeal System received designation as a Breakthrough Device by the FDA.** We ~~received~~ **have funded an independent feasibility study using IDE approval to commence a clinical trial with the AeriSeal System. We shared and sponsored another study to expand the number of clinical data from the full 101- patient cohort in the AeriSeal CONVERT Trial at the 2024 European Respiratory Society Congress in Vienna. The CONVERT Trial data demonstrates that the AeriSeal System is safe and effective in occluding small airways and / or collateral air channels, allowing patients that can be with collateral ventilation to undergo, and benefit from, treated treatment** 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~~ **77.6 % of patients converted from CV to CV-**. If successfully developed and approved, **the AeriSeal System** 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 primary** 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~~ **2024**, we had ~~35~~ **34** patent families in force worldwide. As of December 31, ~~2023~~ **2024**, we had rights to ~~65~~ **71** issued United States patents, ~~15~~ **11** pending United States patent applications, ~~12~~ **114** issued foreign patents and ~~15~~ **13** 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 **System**, ~~StratX~~ **LungTraX Platform**, 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~~ **2025** and ~~2041~~ **2042**. 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~~ **2024**, we had ~~nine~~ **10** 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 **in at 700 Chesapeake Drive, Redwood City, California 94063** where we lease approximately **25-50**, 000 square feet of space. Our lease terminates on July 31, **2025-2035**. ~~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 **the AeriSeal System**, which is still in development, is completely outsourced to a contract manufacturer. The **StratX-LungTraX** Platform' s QCT service is currently outsourced as well. We host the customer- facing web portal for the **StratX-LungTraX** Platform 's QCT service while using a third- party cloud service provider to direct CT scan uploads from customers to **third- party 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 **Quality Management Systems Regulations ("QSR-QMSR ")** 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 II devices, also called Class I reserved devices, also require **are additionally subject to special controls and most are subject to** premarket **review and** 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. Our portfolio of products is regulated in the European Union as a medical device per ~~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~~ **Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to be proposals by legislators at both several providers, including hospitals, and increased the federal and state statute of limitations period for the government levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits recover overpayments to providers from three to five years.** Certain of the European Union Medical Devices Directive (Council Directive 93/42/EEC) (“MDD”) and the Medical Device Regulation (Regulation (EU)..... applicable to our products, and the guidance of the European Commission’s Medical Devices Coordination Group. For those devices **that we place are placing** on the market in **accordance with the EU on the basis of** the transitional provisions of the MDR, we intend to complete conformity assessment procedures **for such 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, issued** 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..... 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~~ **Business associates** ~~Associates~~ **Associates** that create, receive, maintain or transmit individually identifiable health information for or on behalf of a ~~covered~~ **Covered** ~~entity~~ **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 **General Data Protection Regulation (“ 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 disengagement 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 Effectuated 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 **MDR 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, **the AeriSeal System, the Chartis Catheter and the Chartis Console**. 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~~ **Marks**. 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 a CE Certificate of Conformity **in accordance with the MDD and a separate CE Certificate of Conformity in accordance with the MDR** 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 **and a CE Certificate of Conformity** for the Zephyr Valve **in accordance with the MDD. Additionally, we have received a CE Certification of Conformity for the AeriSeal System in accordance with the MDD and we are currently conducting a global clinical trial designed to support PMA approval for the AeriSeal System. We have also obtained a CE Certificate of Conformity in accordance with the MDR for the Chartis Catheter and the Chartis Console**. 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 any of our clinical trial trials~~ 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 **and amendments** to certain aspects of the Affordable Care Act. **On** ~~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 ”) **was signed** 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-current** administration will impact the Affordable Care Act and our business, financial condition and results of operations. **In addition, other legislative changes have..... providers from three to five years.** The **Biden-current** 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 **and the third parties with whom we work** are subject to stringent and evolving obligations related to data privacy and information security. Our **(or the third- parties with whom we work)** 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; **loss of customers;** and other adverse business impacts. In the ordinary course of business, we or the third parties **upon-with** whom we **rely-work**, 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 **including PHI**). 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 **California Consumer Privacy Act (“ 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 **intentional** violation), as well as a private right of action for certain data breaches that is expected to increase data breach litigation. In addition, the **California Privacy Rights Act of 2020 (“ 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, **as well as at the federal and local levels, and we expect more states to pass similar laws in the future**. 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-with** whom we **rely-work**. 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 **information** 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 **or have already adopted** 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. **Regulators in the United States such as the Department of Justice are also increasingly scrutinizing certain personal data transfers and have enacted data localization requirements, including, for example, the executive order on Preventing Access to Americans’ Bulk Sensitive Personal Data and United States Government- Related Data by Countries of Concern issued in February 2024**. 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 incidents~~ 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, **white papers** and other statements, such as **statements related to** compliance with certain certifications or self- regulatory principles, **regarding concerning** data privacy **and**, information security **and artificial intelligence**. **If Regulators in the United States are increasingly scrutinizing these statements, and if** these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, **misleading** 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, **imprisonment of company officials**, 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 **privacy 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 **enacted** ~~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. **As We are not currently classified as a covered entity result of or our LungTrax Platform, we may be considered a business Business associate Associate under HIPAA and thus are not in some circumstances where we would be subject subjected to its requirements or and significant penalties as well as related contractual obligations . However As a Business Associate, we would be responsible for implementing reasonable administrative, physical and technical safeguards as required by HIPAA, including, among other things, maintaining Business Associate Agreements with our customers and our subcontractors that have access to protected health information on our behalf. Moreover,** 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 during~~ the clinical trial process, ~~through in the course of~~ our research collaborations **, via our LungTraX Platform** , 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 to 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** 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 high 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 ~~are subject to incur significant legal, accounting, and other~~ **the reporting requirements of the Exchange Act 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 . **In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts, we fail to comply with evolving laws, regulations, and standards, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. We cannot predict or estimate the amount of additional costs we will incur as a public company or the specific timing of such costs** . 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.