Risk Factors Comparison 2024-02-27 to 2023-02-27 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

An investment in our common stock involves risks. **The** ~~You should consider carefully the~~ following risks, which are discussed more fully in " Item 1A. Risk Factors ", and all of the other information contained in this Annual Report on Form 10- K **should be considered carefully** before investing in our common stock. These risks include, but are not limited to, the following: • that we continue to incur losses; • our ability to attract **, train** and retain key personnel; • our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit ~~agreement~~ **agreements** to which we will remain subject until maturity; • the fluctuation of our financial results from quarter to quarter; • our need to raise additional funding and our ability to obtain it on favorable terms, or at all; • our ability to use net operating losses and research and development credit carryforwards; • our dependence on the success of the Organ Care System, or ~~OCS~~ **OCSTM** ; • our ability to expand access to the OCS through our National OCS Program **, or NOP** ; • our ability to scale our manufacturing and sterilization capabilities to meet increasing demand for our products; • the rate and degree of market acceptance of the OCS; • our ability to educate patients, surgeons, transplant centers and private and public payors on the benefits offered by the OCS; • our ability to improve the OCS platform and develop the next generation of the OCS products; • our dependence on a limited number of customers for a significant portion of our revenue; • our ability to maintain regulatory approvals or clearances for our OCS products in the United States ~~and~~ **, the** European Union **and other select jurisdictions worldwide** ; • our ability to adequately respond to the Food and Drug Administration, or FDA **, or other competent authorities** , follow- up inquiries in a timely manner; • the performance of our third- party suppliers and manufacturers; • our **use of third parties to transport donor organs and medical personnel for our NOP and our ability to maintain and grow our logistics capabilities to support our NOP to reduce** dependence on third **party** ~~parties to transport~~ **transportation** ~~donor organs and medical personnel~~ **, including by means of the acquisition of fixed- wing aircraft for our aviation transportation services** ~~for~~ **or other acquisitions, joint ventures** ~~our~~ **or** ~~National OCS Program~~ **strategic investments; • our ability to maintain Federal Aviation Administration, or FAA, or other regulatory licenses or approvals for our aircraft transportation services** ; • price increases of the components of our products **and maintenance, parts and fuel for our aircraft** ; • the timing or results of post- approval studies and any clinical trials for the OCS; • our manufacturing, sales, marketing and clinical support capabilities and strategy; • attacks against our information technology infrastructure; • the economic, political and other risks associated with our foreign operations; • our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties; • the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally; • regulatory developments in the United States, European Union and other jurisdictions; • the extent and success of competing products or procedures that are or may become available **; • our ability to service our 1. 50 % convertible senior notes, due 2028** ; • the impact of any product recalls or improper use of our products; and • our estimates regarding revenue, expenses and needs for additional financing. PART I Except where the context otherwise requires or where otherwise indicated, the terms " TransMedics, " " we, " " us, " " our, " " our company, " " the company, " and " our business " refer to TransMedics Group, Inc. and its consolidated subsidiaries. Item 1. Business. Overview We are a commercial- stage medical technology company transforming organ transplant therapy for end- stage organ failure patients across multiple disease states. We developed the OCS to replace a decades- old standard of care that we believe is significantly limiting access to life- saving transplant therapy for hundreds of thousands of patients worldwide. Our innovative OCS technology replicates many aspects of the organ' s natural living and functioning environment outside of the human body. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. We have also developed our ~~National OCS Program, or~~ NOP, an innovative turnkey solution to provide outsourced organ retrieval ~~and~~ **,** OCS organ management **and logistics services** , to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS **. Our logistics services include aviation transportation, ground transportation, and other coordination activity** . We believe the use of the OCS combined with the NOP has the potential to significantly increase the number of organ transplants and improve post- transplant outcomes. We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of heart, lung and liver transplantations, making the OCS the only FDA approved, portable, multi- organ, warm perfusion technology platform. All three of our products, OCS Heart, OCS Lung and OCS Liver, have received Pre- Market Approval, or PMA, from the Food and Drug Administration, or FDA ~~. Also~~ , ~~all three of our products, OCS Heart, OCS Lung and OCS Liver are approved~~ for both organs donated after brain death, or DBD organs, and organs donated after circulatory death, or DCD organs. Incidence of end- stage organ failure has been rapidly rising worldwide due to demographic trends that contribute to chronic diseases. Organ transplantation is the treatment of choice for addressing end- stage organ failure due to its positive clinical outcomes and favorable health economics. However, transplant volumes have been significantly restricted by the limitations of cold storage, the standard of care for solid organ transplantation. Cold storage is a rudimentary approach to organ preservation in which a donor organ is flushed with cold pharmaceutical solutions, placed in a plastic bag on top of ice and transported in a cooler. Cold storage subjects organs to significant injury due to a lack of oxygenated blood supply, or ischemia, does not allow physicians to assess organ viability and lacks the ability to optimize an organ' s condition once it has been retrieved from the donor. Time- dependent ischemic injury has been shown to result in short- and long- term post- transplant clinical complications and, together with the inability to assess or optimize

organs, contributes to the severe underutilization of donor organs. With the use of cold storage, the majority of lungs and hearts donated after brain death go unutilized, and almost no available lungs and hearts donated after circulatory death are utilized. We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near- physiologic conditions for donor organs outside of the human body. We designed the OCS technology platform to perfuse donor organs with warm, oxygenated, nutrient- enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. Because the OCS significantly reduces injurious ischemic time on donor organs as compared to cold storage and enables the optimization and assessment of donor organs, it has demonstrated improved clinical outcomes relative to cold storage and offers the potential to significantly improve donor organ utilization. We developed the NOP to provide additional capabilities to transplant centers for the complicated organ procurement process that often requires resources and logistics beyond a transplant center' s existing capabilities and capacity, thereby limiting the number of organs the transplant center may be able to retrieve. Our NOP provides trained organ procurement surgeons, clinical specialists and transplant coordinators that provide an end- to- end clinical solution using our OCS technology. ~~This enables~~ **In 2023, we enhanced our NOP offering to include logistics services with the addition of a logistics team to expand our transportation logistics capabilities. Our logistics services include aviation transportation, ground transportation, and other coordination activity. Our NOP provides** transplant centers **with** the ability to utilize the OCS to procure and transplant more organs for their patients than they would otherwise be able to do without increasing their own staff. **On August 16, 2023, we acquired Summit Aviation, Inc. and Northside Property Group, LLC, or together Summit. Summit was a charter flight operator based in Bozeman, Montana. The acquisition enabled us to add aircraft transportation services to our NOP and become a comprehensive national provider of donor organ retrieval and delivery in the United States. We have also acquired 13 fixed- wing aircraft to transport donor organs as part of the services offered under our NOP. We intend to acquire additional fixed- wing aircraft as we scale our fleet of aircraft to reduce our dependence on third party transportation providers.** We believe the OCS and the NOP ~~will~~ drive significant benefits to all stakeholders in the field of organ transplantation. For patients, we believe the OCS and the NOP provide additional access to life- saving transplants and allow for quicker recovery following transplantation. For hospitals, we believe the OCS and NOP provide a means to increase transplant volume, treat more patients, enhance provider status and improve transplant program economics. Finally, we believe the OCS and NOP provide payors with a more cost- effective treatment for end- stage organ failure and reduces exposure to significant post- transplant complication costs and extended hospital stays. Our OCS products and NOP services are reimbursed in the United States through existing, standard commercial transplant billing mechanisms. The Medicare program and private payors had been providing reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U. S. pivotal trials and have continued providing reimbursement for our products and services following FDA approval. We are in the process of seeking long- term reimbursement for our products outside of the United States. Our corporate headquarters, manufacturing and clinical training facilities are located in Andover, Massachusetts. We also have a geographically distributed team in the United States supporting our **NOP** ~~National OCS Program~~. We have additional distribution and commercial operations in Europe. As of December 31, ~~2022~~ **2023**, we **had 584** ~~employed~~ **employees** ~~212 people globally~~, most of whom were full- time ~~employees~~ **and located in the United States**. We generated $ **241. 6 million, $** 93. 5 million ~~,~~ **and** $ 30. 3 ~~million and $ 25. 6~~ million of total revenue during the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~, respectively, representing year- over- year growth of **158. 5 % and** 208. 8 % ~~and 18. 0 %~~ in **2023 and** 2022 ~~and 2021~~, respectively. Our business model is characterized by a high level of recurring revenue, which is derived primarily from sales of our single- use, organ- specific disposable sets that are required for each transplant using the OCS ~~and~~ **as well as** services provided to transplant centers by our NOP. Our Competitive Strengths We believe the continued growth of our company will be driven by the following competitive strengths: • Only FDA approved, portable, multi- organ, warm perfusion platform Our Organ Care System is the only FDA approved portable, multi- organ, warm perfusion device on the market. Portability is a critical aspect in reducing the ischemic injury to the organ before transplantation, thereby reducing post- transplant complications and allowing the utilization of more organs for transplant. The multi- organ platform allows for the standardization of use across transplant programs. • National OCS Program **We** ~~Our National OCS Program was~~ developed **our NOP** to provide **transplant programs with** a more efficient process to procure donor organs with the OCS. As we expect the number of transplants to increase and the retrieval distance to extend, we believe the field will need alternatives to the current model in which the recipient transplant center sends its team to the donor site for retrieval. Our **NOP** ~~National OCS Program~~ provides a turnkey solution that leverages the technical advantage of the OCS and provides transplant centers with a more efficient way to increase their volume of transplants without significantly increasing resources **. • Transportation Logistics of the NOP Transporting organs, clinical staff and medical technology in the field of organ transplant is very challenging. Donor organs may become available at almost any hospital at any time. The donor organ must be retrieved and transported to allocated recipients in a timely manner while protecting the organ from ischemic injury. The donor site may not be easily accessible and the distance to travel from donor to recipient may be very long. The expansion of our NOP to provide our own transportation logistics services, including 100 % owned and operated private aircraft dedicated to organ retrieval, further improves the efficiency of utilizing the NOP as a complete solution for organ procurement**. • Significant body of strong clinical evidence In order to receive FDA approval for our PMA products, we have conducted a very large number of clinical trials with very large numbers of patient participants, with the results of these trials published in leading medical journals. We ~~have~~ also ~~initiated~~ **continue to collect clinical data through** post- market registries for all of our products and plan to continue to provide the scientific results of these registries to the clinical user community. • Strong relationship with the clinical transplant community The transplant community is highly concentrated in the leading academic medical centers around the world. We have developed strong clinical relationships with many of these centers through their participation in our clinical trials **and their commercial utilization of our products and**

services . In addition, many transplant surgeons at our clinical trial locations may have moved to new centers, bringing their OCS experience with them and allowing our relationships to grow to these new centers. • Expertise in transplant reimbursement and billing The OCS has been reimbursed by the Centers for Medicare & Medicaid Services, or CMS, and private insurers during our clinical trials and continues to be reimbursed in the commercial setting. Since our customers have been billing for reimbursement for many years, we have developed a high degree of expertise in the area of transplant reimbursement and appropriate billing of insurers. We provide advice and best practices to our customers in compliance with laws and regulations. • Strong research and development capabilities and comprehensive intellectual property portfolio We have a long history and broad experience in the development of warm machine perfusion for organ preservation. During the life of our OCS technology platform we have continued to add technological and usability enhancements to our devices. In the future, we intend to develop newer versions of the technology that continue to improve the ease of use, portability, and capability of the products. Organ Transplant Therapy Benefits and Challenges We believe organ transplantation is the most effective treatment for end- stage organ failure in terms of both clinical outcomes and health economics. Organ transplant provides the longest life expectancy and best quality of life compared to other therapies for end- stage organ failure. For example, the therapeutic options for end- stage heart failure include optimum medical management with pharmaceutical treatments, or OMM, mechanical support with a left ventricular assist device, or LVAD, and heart transplantation. Heart transplantation is associated with materially longer survival rates as compared to OMM and LVADs, which are either used as a bridge to transplant or as destination therapy, an alternative to transplant. These improved survival rates, in turn, result in favorable economics for transplantation on the basis of quality- adjusted life years. However, organ transplant therapy faces two major challenges. First, despite the large and growing incidence of organ failure worldwide, and the significant clinical and economic benefits of organ transplantation, the number of transplants severely lags demand due to the limitations of traditional methods of organ preservation prior to transplantation. Second, a high rate of post- transplant clinical complications needs to be reduced to improve outcomes and lower costs. The use of cold static storage for preservation of donor organs contributes to these challenges in three ways: • Subjects the donor organs to severe time- dependent ischemic injury Cold storage deprives the organs from oxygen, resulting in time dependent injury (ischemia). This injury correlates with post- transplant complications and restricts the viable time for organ procurement and transplant, which limits the time and distance possible between donor and recipient and results in low utilization of the donor pool and limits the number of transplant procedures performed annually. • No organ optimization capability Given the non- physiologic environment, cold storage does not allow for any therapeutic interventions to optimize the condition of the donor organs. This further limits utilization of available donor organs for transplantation and could negatively impact post- transplant outcomes. It is well demonstrated that donor organs benefit from some form of optimization to replenish depleted levels of substrates, hormones, and electrolytes that are significantly altered or used up during the donation process. • No organ viability assessment capability During cold storage, the organs are not physiologically active, nor functioning; thus, there are no means for evaluating the suitability of these organs for transplantation. This further limits utilization of available organs as donor populations worldwide are growing older and have concomitant risk factors that benefit from sophisticated diagnostic evaluation capabilities to predict whether the donor organ is suitable and safe to transplant. Our Technology and Solution We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near- physiologic conditions for donor organs outside of the human body. The OCS was designed to perfuse donor organs with warm, oxygenated and nutrient- enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. The OCS Technology Platform We developed the OCS, the first and only FDA approved portable, multi- organ, warm perfusion platform, to leverage proprietary core technologies across multiple organs. For each OCS product, we supplement the platform with organ- specific, customized and proprietary technologies. To date, we have developed three OCS products, one for each of lung, heart and liver transplantation. **We have initiated the development of the next generation multi- organ platform to improve the usability, incorporate new technology and automation, and facilitate the use of** OCS **in our NOP** ~~products for additional organs are under development~~ . Each OCS product consists of three primary components customized for each organ: • OCS Console: The OCS Console is a highly portable electromechanical medical device that houses and controls the function of the OCS and is designed to fit in the current workflow for organ transplantation. • OCS Perfusion Set: The OCS Perfusion Set is a sterile, biocompatible single- use disposable set that stores the organ and circulates blood. The OCS Perfusion Set includes all accessories needed to place the organ on the system. • OCS Solutions: The OCS Solutions are a set of nutrient- enriched solutions used with blood to replenish depleted nutrients and hormones needed to optimize the organ' s condition outside of the human body. The OCS technology platform is equipped with the following core technologies that we designed to comprehensively address the limitations of cold storage and improve transplant outcomes: • proprietary pulsatile blood pump to simulate beating heart perfusion in organs outside of the human body; • proprietary software- controlled titanium blood warmer to maintain blood at body temperature while maximizing portability; • gas exchanger to maintain organ oxygenation outside of the human body; • customized hemodynamics sensors to monitor and assess organ function outside of the human body; • proprietary software- controlled, miniaturized, electromechanical system with universal power supply and hot- swappable batteries to maximize portability and travel distance for organ retrieval; • proprietary wireless monitor and control software to provide an intuitive user interface for monitoring critical organ function; and • customized carbon fiber OCS console structure to reduce the overall weight of the system and maximize portability. Key Advantages of the OCS Platform We believe the OCS platform provides significant benefits relative to cold storage: • Significant reduction in ischemia Decreases current time and distance limitations on organ transport while also increasing the currently limited time period for retrieval during which high quality transplant outcomes can reliably be obtained. This maximizes organ utilization and enables increased access to organ

transplantation, while also meaningfully improving post- transplant outcomes. • Enables organ optimization outside of the human body Allows therapeutic optimization of donor organs from the damaging conditions of brain and circulatory death using clinically proven and safe modalities, thus significantly improving donor organ utilization and patient outcomes. • Allows for organ viability assessment Enables diagnostic evaluation of the donor organ using currently acceptable clinical standards to evaluate the organ' s suitability for transplantation and to maximize the post- transplant outcomes. We believe that by comprehensively addressing the three limitations of cold static storage, the use of the OCS will allow for increased utilization of donor organs and improve post- transplant outcomes. Benefits of the OCS Platform for Key Stakeholders We believe the OCS platform provides significant benefits to key constituents across the transplant continuum. Value to Patients We believe the OCS increases patients' access to what we believe is the best treatment option for end- stage organ failure, which results in improved quality of life and longer life expectancy. In addition, we believe improved clinical outcomes from use of the OCS will allow patients to recover more quickly following a transplant. Value to Providers We believe the OCS allows providers to improve clinical outcomes and increase the number of patients who receive organ transplants. Improvements in clinical outcomes could enable providers to meet the CMS post- transplant survival metrics required for reimbursement coverage and improve the overall financial profile of their transplant programs. In addition, we believe the increase in transplant volumes enabled by the OCS will help providers achieve " Center of Excellence " designations with payors and thus drive significant revenue growth for their transplant programs. Value to Payors We believe organ transplantation is a cost- effective treatment for end- stage organ failure as it provides the longest life expectancy, and better quality of life, compared to other treatments like mechanical support or medical therapy. We believe the OCS will enable payors to benefit from these favorable health economics and limit their exposure to the high cost of severe post- transplantation complications and extended hospital stays. Our Strategy We are committed to our goal of transforming organ transplantation with our OCS platform by establishing the OCS as the standard of care for solid organ transplantation and thereby increasing the utilization of donor organs and improving clinical outcomes. The key elements of our strategy are: • Grow the adoption of the OCS at existing transplant center customers and expand the number of centers utilizing OCS and NOP. We are focused on driving adoption of the OCS and NOP at leading, high volume transplant programs as well as expanding utilization to medium and smaller centers that can utilize OCS and NOP to provide transplants to more patients. • Grow our **NOP** ~~National OCS Program~~ , a turnkey solution to provide outsourced organ retrieval ~~and~~ **, OCS** organ management **and logistics services** , to provide transplant programs with a more efficient process to procure donor organs with the OCS. **Our NOP** ~~We have initiated a service program that~~ leverages our clinical ~~and~~ **,** logistical **and transportation** capabilities to provide access to and use of the OCS for ~~transplant centers in certain regions of the United States. We believe we could become a national clinical service provider of organ retrieval and perfusion service to~~ transplant centers throughout the United States. We believe this program has the potential to accelerate adoption of the OCS, maximize utilization of donor organs for transplantation and, by standardizing the quality of use of the OCS, deliver better clinical outcomes. • Develop the next generation OCS technology platform to improve user experience and facilitate our **NOP** ~~National OCS Program~~ . We have initiated the development of the next generation multi- organ platform to improve the usability, incorporate new technology and automation, and facilitate the use of OCS in our ~~National OCS Program~~ **NOP. In addition, in August 2023, we acquired certain assets related to lung and heart perfusion technology from Bridge to Life, and we intend to further develop these technologies to expand our product offerings and indications for organ transplantation** . • Expand internationally by accessing national reimbursement for OCS in key European countries. We have begun the development of required comprehensive material for various national healthcare systems throughout Europe. We believe international expansion will be an additional growth driver for us in the long term. Commercialization We commercialize our products through two channels: our NOP and a direct acquisition model. Our NOP enables transplant centers to outsource the retrieval ~~and~~ **,** organ management **and transportation logistics** process to our trained organ procurement surgeons, clinical specialists and transplant **and logistics** coordinators using our OCS products. Our offering allows the transplant center to focus their internal resources on the transplant surgery and patient care. Utilizing our NOP saves the transplant center from investing in additional resources to support higher volumes and longer distance retrievals. Since the launch of the NOP, our sales of the OCS have primarily been through the NOP. Our direct acquisition model is provided to transplant centers **to** ~~who are interested in training~~ --- **train** their own teams for retrieval and organ management on the OCS. Customer users are certified on the use of OCS at our training facility. Customers in the direct acquisition channel keep inventory of OCS disposables available and order replenishment as they are used. All of our international customers and a small number of our U. S. customers purchase our OCS products through the direct acquisition model. Reimbursement Medicare' s reimbursement for organ transplant procedures is well- established and involves two payment mechanisms. The first is the inpatient hospital prospective payment system, which reimburses the transplant hospital for operating costs incurred during the inpatient stay in which the transplant procedure is performed. The payment for this stay is determined by the Medicare Severity- Diagnosis Related Group, or MS- DRG, into which the case is assigned. The second mechanism involves a separate payment, in addition to the MS- DRG- based payment, for organ acquisition costs, which include organ preservation and transportation costs. Medicare reimburses hospitals for allowable organ acquisition costs on a reasonable cost basis. The OCS is reimbursed under this second mechanism. For Medicaid transplant recipients, reimbursement to a transplant hospital for the incurred cost of the OCS is determined based on the applicable state Medicaid program. Some states establish a global payment for the transplant and organ acquisition costs, and some states have separate payments for the inpatient stay based on the MS- DRG system and for organ acquisition costs. Private insurers typically have agreements as to how they reimburse for the transplant costs and the organ acquisition costs, which may be through a global payment for both, or a payment for the transplant and a separate mechanism for paying for organ acquisition costs. Nearly half of U. S. lung, heart and liver transplants are covered under the Medicare and Medicaid programs, with the remainder being reimbursed through private payors. Medicare and private payors provided reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U. S. pivotal trials and have provided reimbursement for the OCS Lung, OCS Heart and OCS Liver

following their FDA approvals. This has established multiple years of billing precedent. We believe these established methods will continue to facilitate commercial reimbursement for the OCS Lung, OCS Heart and OCS Liver. Reimbursement outside of the United States follows a similar overall structure; however, reimbursement decisions are required in each individual country and may require national health systems to review and approve OCS reimbursement for each organ- specific product. Currently, national healthcare systems do not reimburse transplant centers for the use of the OCS and reimbursement in international markets may require us to undertake additional clinical studies. However, international hospitals using the OCS currently pay for the OCS from their hospital budget or charitable funds. We are in the process of seeking long- term reimbursement for our OCS products in several jurisdictions. Clinical Evidence The lead transplant surgeons at transplant centers are clinically focused and rely primarily on clinical evidence to drive changes in their practice of organ transplantation. We have developed a substantial body of global clinical evidence to support our FDA PMA approvals and PMA submissions for the OCS for lung, heart and liver transplantation. Many of these clinical trials and studies have been published in peer- reviewed clinical journals. Our clinical trials have evaluated the use of the OCS for transplantation of organs that meet the current criteria for organ transplantation, as well as organs that would otherwise go unutilized from DBD and DCD donors. We believe the results of our clinical trials across lung, heart and liver transplantation may support the potential of the OCS in improving clinical outcomes and increasing utilization of available donor organs. The results of our clinical trials are summarized in the images below. OCS Clinical Trial Overview Table Intellectual Property Patents and Trade Secrets We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure and assignment of inventions agreements and other measures to protect our intellectual property. Our patent portfolio includes patents and patent applications that we own or license from third parties. As of December 31, ~~2022~~ **2023**, our owned and licensed patent portfolio consisted of approximately ~~297~~ **400** issued patents and pending patent applications worldwide, including in the United States, Australia, Europe, Canada, China, Israel, New Zealand and Japan. Our owned portfolio includes patents and applications related to one or more of the OCS Lung, OCS Heart, OCS Liver and solutions. In the United States, our owned portfolio includes about ~~29~~ **45** issued patents and ~~10~~ **13** pending applications. Outside the United States, our owned portfolio includes about ~~209~~ **288** issued patents and ~~49~~ **54** pending applications. Issued patents in our portfolio are expected to expire between 2025 and ~~2036~~ **2038**, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. If granted, the pending U. S. and foreign patent applications in our portfolio are expected to expire between 2025 and ~~2036~~ **2043**, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. As of December 31, ~~2022~~ **2023**, our patent portfolio relating to the OCS Lung **or lung transplantation technology** includes **families** ~~a family~~ comprised of patents and patent applications with claims that are generally directed to certain methods and systems for preserving a lung ex vivo using both perfusion and ventilation. Such patents are issued in the United States, Australia, Belgium, Canada, China, Denmark, Europe, France, Germany, Ireland, Israel, Italy, Japan, Hong Kong, Netherlands, New Zealand, Spain, Sweden, and United Kingdom, and patent applications are pending in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, Japan and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in ~~2029~~ **2043**, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. As of December 31, ~~2022~~ **2023**, our patent portfolio relating to the OCS Heart **or heart transplantation technology** includes **families** ~~a family~~ comprised of patents and patent applications with claims that are generally directed to certain methods and systems for preserving a heart ex vivo. Such patents are issued in the United States, Australia, Belgium, Canada, China, Denmark, Europe, France, Germany, Hong Kong, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Spain, Sweden, and United Kingdom, and patent applications are pending in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, Japan, and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in ~~2036~~ **2038**, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. We have requested patent term extension for one patent relating to the OCS Heart, U. S. Patent No. 7, 651, 835, which, if granted, would expire in 2032. As of December 31, ~~2022~~ **2023**, our patent portfolio relating to the OCS Liver **or liver transplantation technology** includes a family of issued and pending patent applications with claims that are generally directed to certain systems, including perfusion circuits for perfusing a liver ex vivo. Such patents are issued in the United States and Australia, and applications are pending in the United States, Australia, Canada, China, ~~Europe,~~ Hong Kong, Israel, Japan and New Zealand. This patent and any patents issued from pending patent applications are expected to expire in 2035, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. We have requested patent term extension for one patent relating to the OCS Liver, U. S. Patent No. 10, 076, 112, which, if granted, would expire in 2035. As of December 31, ~~2022~~ **2023**, our patent portfolio relating to the OCS Solutions **or other solutions for transplantation systems** includes **families** ~~a family~~ comprised of patents and patent applications with claims that are generally directed to compositions of certain perfusion fluids. Such patents are issued in the United States, Australia, China, Israel, Japan, New Zealand and patent applications are pending in the United States, Canada, China, Europe, Hong Kong, and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in ~~2032~~ **2035**, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. 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 filing date of a non- provisional patent application in the applicable country. We cannot assure ~~you~~ that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop methods or devices that are not covered by our patents. Furthermore, numerous U. S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or proprietary

technologies may be alleged to infringe. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know- how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using the OCS, any of which could severely harm our business. For more information, see " Item 1A. Risk Factors — Risks Related to Our Intellectual Property " in this Annual Report on Form 10- K. Competition Competition in organ preservation for transplantation can be classified into two main segments: (1) cold storage and cold perfusion technologies and (2) warm perfusion technologies. In both cold storage and cold perfusion, the organs are not functioning ~~or~~ **and are** metabolically inactive. The characteristics of cold storage and cold perfusion described above significantly limit donor organ utilization and are a primary driver of post- transplant complications. Supply of cold storage and cold perfusion products is fragmented with a number of companies mainly providing undifferentiated flush and perfusion solutions or temperature controlled cold storage devices. Warm perfusion preservation for solid organ transplant is an emerging alternative designed to address the limitations of cold storage and cold perfusion. In warm perfusion, the organs are functioning and metabolically active. We are aware of only two other companies providing warm perfusion systems, OrganOx Limited and XVIVO Perfusion AB, both of which offer single- organ warm perfusion systems for the liver and lung, respectively. We believe that our principal competitive factors include: • strong clinical evidence from large trials demonstrating safety, effectiveness and clinical benefits; • superior technology; • our NOP **, including clinical service and logistics services** ; • regulatory approvals for broad clinical indications of use; • ease of integration into current organ retrieval workflow, including system portability across all modes of transportation; • platform capabilities designed to support multiple organ transplant programs; • brand recognition among leading transplant programs worldwide; • established clinical relationships and a core of committed clinical users; • commercial reimbursement; and • sophisticated clinical training and support program to users worldwide. Research, Development and Clinical Trial Operations Our research, development and clinical trial operations function consists of a dedicated clinical trial team that has trial management, data collection and biostatistics expertise. Our product engineering function consists of ~~a~~ multi- disciplinary engineering ~~team~~ **teams** that ~~has~~ **have** electrical, mechanical, systems and software engineering expertise. Our regulatory function includes a team with both U. S. and international medical device regulatory expertise and is supported by senior FDA regulatory advisors and outside legal counsel. For the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ our research, development and clinical trials expenses were $ **36. 1 million, $** 26. 8 million ~~,~~ **and** $ 22. 3 ~~million and $ 18. 8~~ million, respectively. This team is focused on the following research, development and clinical trial activities: • developing the next generation **OCS; • developing applications to expand the access and use of the data generated from the** OCS; • expanding the body of clinical evidence supporting the use of the OCS platform through pre- market clinical trials, post- market registries and scientific publications; • improving incrementally the technology and manufacturing efficiency of our current platform; and • conducting research to investigate new clinical applications and uses for the OCS platform. Manufacturing ~~,~~ **and** Supply ~~and~~ **Chain** Operations We design and assemble our OCS Consoles and disposable OCS Perfusion Sets at our facility in Andover, Massachusetts. We have recently increased the size of our manufacturing facility at the Andover site ~~and expect this~~ to ~~be certified by the FDA in the near~~ **increase our manufacturing capacity to meet current and** future **demand** . We believe this expanded facility' s capacity is sufficient to cover the next several years of forecasted demand. We have added a second shift to our existing cleanroom and we have the ability to add additional shifts to the new, expanded, cleanroom to further increase production capacity. We manufacture our sterilized disposable OCS Perfusion Sets in a class 10, 000 cleanroom. We source many of the components for the OCS Console and OCS Perfusion Sets from third- party suppliers that are required to manufacture and test them according to our specifications. We purchase some of the components of the OCS Console and OCS Perfusion Set from single- source suppliers and, in a few cases, sole- source suppliers. We rely on third parties to sterilize our products prior to sale. We source the OCS Solutions using our proprietary formulas from third- party suppliers. Fresenius is our single- source supplier of OCS Solutions for the OCS Lung and OCS Heart. Our agreement with Fresenius for the supply of OCS Lung Solution was ~~originally~~ **previously** through April ~~2022~~ **2024** and was automatically extended for 24 months through April ~~2024~~ **2026** . Upon expiration the agreement will continue to extend for subsequent periods of 24 months each, unless terminated by either party at least 12 months prior to the end of the initial term or the then- current extension term. We may also terminate this agreement with 12 months' notice if we request that Fresenius qualifies a second manufacturing plant or qualifies a reputable third party to manufacture the OCS Lung Solution and Fresenius fails to respond to this request. Our agreement with Fresenius includes an obligation to meet certain annual minimum purchase commitments based upon rolling order forecasts that we provided to Fresenius in accordance with this agreement. Our agreement with Fresenius for the supply of OCS Heart Solution has one- year evergreen terms, terminable by either party at least 12 months prior to the end of the then- current term. Our **supply chain and** operations team includes **supply chain procurement and planning,** production and test employees **, sustaining engineers** , manufacturing engineers and field service technicians. **Product** Regulation Our OCS products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in the European Union and other countries. Our products are subject to regulation as medical devices under the Federal Food, Drug and Cosmetic Act, or FDCA, as implemented and enforced by the FDA. The FDA regulates the development, design, non- clinical and clinical research, manufacturing, safety, effectiveness, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA. In addition to U. S. regulations, we are subject to a variety of regulations in the European Union and other countries, governing medical devices, clinical investigations and commercial sales

and distribution of our products. Regardless of whether we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain the relevant authorizations / approvals before commencing clinical trials / investigations and to obtain the necessary authorizations, approvals or certifications of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials / investigations or commercialize our products in those countries. In the European Union, the manufacturer of a device must affix a Conformité Européene mark, or CE Mark, which allows the device to be placed on the market anywhere in the EU and additional Member States of the European Economic Area, or EEA, (i. e., Norway, Lichtenstein and Iceland). The EU CE mark is also recognized in Turkey and, for a transitional period following the UK' s withdrawal from the European Union, referred to as Brexit, in the United Kingdom. The authorization / approval processes for devices outside the European Union will vary from country to country and the time may be longer or shorter than that required for FDA clearance or approval or EU CE marking. FDA Premarket Clearance and Approval Requirements Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510 (k) premarket notification, approval of a PMA or issuance of a de novo classification order. 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 and regulatory controls needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and / or the user and are those for which safety and effectiveness can be reasonably assured by adherence to the FDA' s general controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and device malfunctions, and truthful and non- misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA' s General Controls and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510 (k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510 (k) of the FDCA requesting a substantial equivalence determination that provides permission to commercially distribute the device. The FDA' s permission to commercially distribute a device subject to a 510 (k) premarket notification is generally known as 510 (k) clearance. Under the 510 (k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is " substantially equivalent " to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or a device that was reclassified from Class III to Class II or I, or another commercially available device that was cleared through the 510 (k) process or that was granted marketing authorization through the de novo classification process under section 513 (f) (2) of the FDCA **, or a 510 (k) exempt device** . We received 510 (k) clearance for the OCS Lung Solution for cold flush, storage and transportation of donor lungs in July 2021, ~~and~~ for the OCS Lung Donor Flush Set in November 2022 **, and for the OCS Heart Leukocyte Reducing Filter in October 2023** . Devices deemed by the FDA to pose the greatest risks, such as life- sustaining, life- supporting and many implantable devices, or devices that have been found not substantially equivalent to a legally marketed Class I or Class II predicate device, are placed in Class III, requiring approval of a PMA. Each of our OCS warm perfusion products is a Class III device. We have received a PMA for each of the following: • OCS Lung for the preservation of standard criteria donor lungs for double- lung transplantation; • OCS Lung for the preservation of donor lungs initially deemed unsuitable due to limitations of cold storage for double- lung transplantation; • OCS Heart for the preservation of DBD donor hearts deemed unsuitable due to limitations of cold storage (e. g. > 4 hours of cross- clamp time); • OCS Heart for the ex vivo reanimation, functional monitoring, and beating- heart preservation of donation- after- circulatory- death (DCD) hearts; and • OCS Liver for the preservation of DBD and DCD donor livers < 55 years old, macrosteatosis < 15 % and with < 30 minutes of warm ischemia time. PMA Pathway Class III devices require an approved PMA before they can be marketed. The PMA process is more demanding than the 510 (k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA' s review generally takes one year, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained. An advisory committee of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel' s recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third- party manufacturers' manufacturing facility or facilities to ensure compliance with the QSR and, in some cases, will audit the applicant and clinical sites as part of its Bioresearch Monitoring program. During the PMA review, the FDA assesses whether the data and information in the PMA constitute valid scientific evidence to support a determination that there is a reasonable assurance that the device is safe and effective for its intended use (s) based on the proposed labeling. The FDA may approve a PMA with post- approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long- term follow- up data from patients in the clinical study that supported a PMA or requirements to conduct additional clinical studies post- approval. The FDA may condition a PMA approval on some form of post- market surveillance when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval. Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design or performance specifications, which affect the safety or effectiveness of the device, require submission and approval of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA,

except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory committee. Certain other changes to an approved device require the submission and approval of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. Clinical Trials Clinical trials are almost always required to support a PMA application and may be necessary to support PMA supplements for additional indications or modified versions of a marketed device product. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA' s investigational device exemption, or IDE, regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of study review and approval, informed consent, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a " significant risk " to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. To be approved, an IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device to support marketing approval or clearance, or to warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects. Non- significant risk device studies do not require submission of an IDE application to FDA. In the United States, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB. The IRB is responsible for the initial and continuing review of the study and may pose additional requirements for the conduct of the study. During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. After a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits or protocol violations. Post- market Regulation After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include: • establishment registration and device listing with the FDA; • QSR requirements, which require manufacturers, including third- party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process; • labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or " off- label " uses and impose other restrictions on labeling; • approval of a PMA supplement for certain modifications to PMA- approved devices that affect the safety or effectiveness of the device, or clearance of a new 510 (k) premarket notification for modifications to 510 (k) cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of the device; • medical device reporting regulations, which require that a manufacturer report to the FDA information that reasonably suggests a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur; • correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; • complying with the federal law and regulations requiring Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA' s Global Unique Device Identification Database; • the FDA' s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death; and • post- market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master record, device history file, and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shutdown of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off- label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls. The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions: • warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties; • recalls, withdrawals, or administrative detention or seizure of our products; • operating restrictions or

partial suspension or total shutdown of production; • refusing or delaying requests for approvals of PMAs of new products or modified products; • withdrawing a PMA approval that has already been granted; • refusal to grant export **permits** or **certificates** ~~import approvals~~ for our products; or • criminal prosecution. Regulation of Medical Devices in the European Union In the European Union, our products are regulated as medical devices. Regulation of our medical devices in the European Union is harmonized through Regulation (EU) 2017 / 745, or the MDR, which repealed and replaced the Medical Devices Directive (93 / 42 / EEC) with effect from May 26, 2021. However, the competent authorities in each member state enforce the standards set out in the MDR against relevant economic operators (including the manufacturer, importer, authorized representative and distributors) making medical devices available in the member state (although, under the MDR there are provisions for national competent authorities to inform other competent authorities, the European Commission and Notified Bodies, as applicable, of certain non- compliances). Under the MDR, a medical device placed on the market in the European Union must meet the applicable General Safety and Performance Requirements, or GSPRs, laid down in Annex I of the MDR. Similar to the U. S. system, medical devices are classified into one of four classes based on risk: I, IIa, IIb and III, with class I representing the lowest risk products and class III the highest risk products. One of the most fundamental GSPRs is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others (provided that any risks posed are acceptable when weighted against the benefits). In addition, the GSPRs include (but are not limited to) that the device must achieve the performances intended by the manufacturer, be designed, manufactured and packaged in a suitable manner and the manufacturer must establish, implement, document and maintain a risk management plan. The European Commission has adopted various standards applicable to medical devices, referred to as harmonized standards. While not mandatory, compliance with these harmonized standards is often viewed as the easiest way to satisfy the GSPRs as a practical matter. Compliance with a harmonized standard developed to implement a GSPR also creates a rebuttable presumption that the device satisfies that essential requirement. Currently the European Commission has only harmonized a relatively limited number of standards (these include, for example, standards of sterilization, biological evaluation, the quality management system, etc.) but the Commission will continue to harmonize more standards. To demonstrate compliance with the GSPRs, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post- market experience in respect of similar products already marketed. For all devices other than low risk devices (i. e., Class I non- sterile, non- measuring devices), a conformity assessment procedure requires the intervention of a notified body. The notified body must audit and examine a product' s technical dossier and the manufacturer' s quality system. If satisfied that the relevant product conforms to the relevant GSPRs, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then affix the CE Mark to the device, which allows the device to be placed on the market throughout the European Union (and by extension the European Economic Area). Once the product has been placed on the market in the European Union, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device. The notified body has ongoing audit rights and must be notified of all significant changes to the device. Although the MDR now applies so all new devices placed on the market must be CE marked under it, under the transition period granted by the MDR, certificates issued by notified bodies for medical devices under the Medical Devices Directive before May 26, 2021 **may** remain valid **and the devices may continue to be placed on the EU market potentially** until the ~~period indicated~~ **end of December 2027 or 2028 (depending** on the ~~certificate~~ **class of device) and provided the manufacturer satisfies certain requirements** , **including that** ~~subject to all certificates becoming void on May 27, 2024. Therefore, so long as~~ there are no significant changes in the design and intended purpose of these devices ~~, the devices can continue to be placed on the market until the date the Medical Devices Directive certificate becomes void~~ . The requirements of the MDR are significantly more onerous than under the EU Medical Devices Directive. The increased regulation includes the following: • strengthening of the rules on placing devices on the market, by requiring more evidence substantiating safety and efficacy of the device and more detailed content in the technical documentation for each device; • requiring a structured post- market clinical follow- up program for every medical device; • necessitating more thorough post- market surveillance program, with an emphasis on active gathering and analyzing the data; • establishing explicit provisions on manufacturers' responsibilities for the follow- up of the quality, performance and safety of devices placed on the market and new responsibilities for distributors and importers; • improving the traceability of medical devices throughout the supply chain to the end- user or patient through a unique identification number; • setting up a central database into which manufacturers and other economic operators are required to input data with the goal of providing EU competent authorities as well as provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and • strengthening rules for the assessment of certain high- risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market. All of our products that were previously certified under the EU Medical Devices Directive, including OCS Heart ~~and~~ **,** OCS Lung **, and OCS Liver** systems, ~~both of~~ which includes the OCS Console, the OCS disposables, and the OCS solution additives ~~, and the OCS Liver Console and disposables~~ , have now been recertified under the MDR. We ~~have also applied for and expect to receive~~ **received** the CE Mark for the OCS Liver combined with our solution additives under the MDR **in May 2023,** ~~within~~ -- **with** ~~the next 12 months~~ **an effective date of April 2023** . Clinical Investigations Clinical evidence is required for most medium and high risk devices. In some cases, a clinical study may be required to support the CE marking of a device. A manufacturer that wishes to conduct a clinical study involving the device is subject to the clinical investigation requirements of the MDR, EU member state requirements, and current good clinical practices defined in harmonized standards and guidance documents. Clinical investigations for medical devices cannot proceed without a positive opinion of an ethics committee and approval by or notification to the relevant national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may

request a copy of the final study report. Post- marketing Requirements In the European Union, we are currently required to comply with strict post- marketing obligations that apply after a device is placed on the market. These include the obligation to have in place a post- market surveillance system and vigilance system. These requirements include that the manufacturer must report to the relevant national competent authorities any serious incident involving devices made available on the market and any field safety corrective action in respect of devices made available on the market or undertaken in a third country in relation to a device made available on the market. Additionally, the manufacturer of high risk devices must submit periodic safety update reports to its notified body and manufacturers of lower risk devices must maintain periodic safety update reports as part of the technical documentation for their products. Authorities in the European Union also closely monitor the marketing programs implemented by device companies. The MDR prohibits making misleading claims, including promoting the product for or suggesting a use that is not part of its intended purpose. However, the obligations that companies must fulfill concerning premarketing approval of promotional material vary among member states of the European Union as beyond that requirement, advertising and promotion law for medical devices is not harmonized in the European Union. Regulations Applicable to Transport of Organs Intended for Transplantation In the European Union, Directive 2010 / 53 / EU sets out certain standards which the EU member states should apply in respect of procurement, preservation and transport of organs intended for transplantation. While we are not directly affected by this directive, our EU customers are, and our products may either help or impede their compliance with this Directive. Regulation of Medical Devices in the United Kingdom The Medicines and Healthcare products Regulatory Agency, or the MHRA, is responsible for regulating the UK medical devices market. The MHRA performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK. The MHRA is also responsible for the designation and monitoring of UK approved bodies (the equivalent of EU notified bodies). Since May 26, 2021, the EU Medical Devices Regulation (Regulation 2017 / 745), or the EU MDR, has applied in EU Member States and Northern Ireland. Further, the In Vitro Diagnostic Medical Devices Regulation (Regulation 2017 / 746), or the EU IVDR, has applied in EU Member States and Northern Ireland since May 26, 2022. As these EU regulations took effect after the UK left the European Union, they were not EU law automatically retained by the EU (Withdrawal) Act 2018 and therefore do not and will not apply in Great Britain (England, Wales and Scotland). In the United Kingdom medical devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which give effect in UK law to the directives listed below (which have now been repealed and replaced in the European Union by the EU MDR and EU IVDR): • Directive 90 / 385 / EEC on active implantable medical devices (EU AIMDD) • Directive 93 / 42 / EEC on medical devices (EU MDD) • Directive 98 / 79 / EC on in vitro diagnostic medical devices (EU IVDD) This means that the Great Britain route to market is based on the requirements derived from the above EU legislation and is thus different to the route to market for the European Union. **However, although neither the EU MDR nor EU IVDR apply in Great Britain, the UK MDR 2002 provide a transitional period that allows manufacturers to place devices CE marked under the EU MDR or EU IVDR (including their relevant transition periods), on the market in Great Britain potentially up until June, 30 2030.** Since January 1, 2021 (when the Brexit transition period ended), there have been a number of changes, introduced through secondary legislation, on how medical devices are placed on the market in Great Britain (England, Wales and Scotland). These include: • a new route to market and product marking (the UKCA marking) is available for manufacturers wishing to place medical devices on the Great Britain market; • all medical devices, including in vitro diagnostic medical devices, or IVDs, custom- made devices and systems or procedure packs, need to be registered with the MHRA before they are placed on the Great Britain market; • medical device manufacturers based outside the UK who wish to place a device on the Great Britain market need to appoint a single UK Responsible Person for all devices who will act on their behalf to carry out specified tasks, such as registration ~~; • CE marking will continue to be recognized in Great Britain until June 30, 2024; • certificates issued by EU- recognized Notified Bodies will continue to be valid for the Great Britain market until June 30, 2024~~ ; • the EU no longer recognizes UK Notified Bodies and UK Notified Bodies are not able to issue CE certificates. (Following Brexit, certificates issued by our UK notified body (BSI UK) were no longer recognized for CE marking purposes. BSI Netherlands thus reissued the certificates that allow CE marking of the OCS products); and • UK Notified Bodies have become UK Approved Bodies. UK Approved Bodies can issue UKCA marking certificates. We have appointed a UK Responsible Person for our devices in the UK. In order to demonstrate compliance with the essential requirements of the UK MDR 2002 and the general safety and performance requirements of the EU MDR, and in order to justify the application of UKCA / CE / CE UKNI marking, it will sometimes be necessary for the manufacturer of the device to provide clinical data with which to back up claims made for that device. This may involve the need for a specifically designed clinical investigation to: • verify that under normal conditions of use the performance characteristics of the device are those intended by the manufacturer; and • determine any undesirable side- effects and to assess whether these are acceptable risks when weighed against the intended performance of the device. If such an investigation is necessary, **and will be conducted in the UK,** the manufacturer must make an application to the MHRA before the investigation is due to begin, and such a clinical investigation may only proceed provided no grounds for objection are raised by the MHRA within the statutory review time constraint. The MHRA will reach a decision aided by a number of expert assessors. It is the responsibility of the manufacturer both to notify the MHRA and to submit the documentation required by the UK MDR 2002 to the MHRA. The clinical investigator will normally have no direct contact with the MHRA **. The manufacturer must also obtain ethics committee approval for the investigation** . Once a medical device has been placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device. They must also take appropriate safety action when required. The manufacturer must also ensure their device meets appropriate standards of safety and performance for as long as it is in use. The advertising and marketing of medical devices is governed in the UK by both legislation and self- regulatory codes of practice. The MHRA Enforcement of Medical Device Regulations in the UK To ensure that medical devices placed on the market and put into service in the UK meet applicable regulatory requirements the MHRA perform the following activities: •

assess all allegations of non- compliance brought to them, using a risk- based system; • monitor the activity of UK Approved Bodies designated by MHRA to assess the compliance of manufacturers; and • investigate medical devices as a result of adverse incident reports or intelligence indicating a potential problem. If MHRA considers that a person or company has committed a serious offense by failing to comply with applicable regulations or the conditions of a notice issued then a person / company may be subject to prosecution. UK Regulations Applicable to Organs Intended for Transplantation The standards for the quality and safety of organs for transplantation has been enacted into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended. This Regulation allows for the establishment of a Competent Authority for the regulation of organ transplantation. In the UK the Competent Authority is the Human Tissue Authority, which has published the " The Quality and Safety of Organs Intended for Transplantation: a documentary framework " which details mandatory requirements as well as guidance on how those requirements may be met. While we are not directly affected by this Regulation and guidelines, our UK customers are, and our products may either help or impede their compliance with this Regulation. Regulation in Other Countries We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of: • design, development, manufacturing and testing (including with respect to significant changes to the products); • product standards; • product safety; • product safety reporting; • marketing, sales and distribution; • packaging and storage requirements; • labeling requirements; • content and language of instructions for use; • clinical trials; • record keeping procedures; • advertising and promotion; • recalls and field corrective actions; • post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; • import and export restrictions; • tariff regulations, duties and tax requirements; • registration for reimbursement, agreement of prices with government; and • necessity of testing performed in country by distributors for licensees. The time required to obtain clearance by foreign countries may be longer or shorter than that for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements. **We received a Class II Medical Device License from Health Canada for our OCS Liver combined with our solution additives in October 2023 to complement our existing Health Canada licenses for OCS Heart and OCS Lung.** Adverse events and potential adverse events are monitored closely by regulatory authorities. For example, if, as a result of manufacturing error, the efficacy of our products does not meet the standards claimed in the accompanying instructions for use, regulatory authorities could prevent our products from being placed on the market. Internationally, the approaches to product defects will vary. A product may be recalled in one country but not in others. Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal, state, international laws, as well as laws with extra- territorial effect and market practices restrict our business practices. These laws include, without limitation, U. S. and foreign laws intended to prohibit or otherwise regulate activities that might result in fraud, abuse and bribery. U. S. Laws U. S. federal healthcare fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The principal U. S. federal healthcare fraud and abuse laws applicable to us and our activities include: (1) the Anti- Kickback Statute, which prohibits the knowing and willful offer, solicitation, payment or receipt of anything of value in order to generate business reimbursable by a federal healthcare program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally- funded healthcare program, including claims resulting from a violation of the Anti- Kickback Statute; and (3) healthcare fraud statutes that prohibit false statements and improper claims to any third- party payor. There are also similar state anti- kickback and false claims laws that apply to activities involving state- funded Medicaid and other healthcare programs as well as to private third- party payers. The Anti- Kickback Statute is particularly relevant because of its broad applicability. Specifically, the Anti- Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Almost any financial interaction with a healthcare provider, patient or customer will implicate the Anti- Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. Only those interactions that represent fair market value exchanges, however, are generally protected by an exception or safe harbor. The government can exercise enforcement discretion in taking action against unprotected activities. Many interactions in which we commonly engage, such as the provision of business courtesies to healthcare practitioners, could implicate the Anti- Kickback Statute and may not be protected by an exception or safe harbor. If the government determines that these activities are abusive, we could be subject to enforcement action. Penalties for Anti-Kickback Statute violations may include both criminal penalties such as imprisonment and civil sanctions such as fines and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Exclusion would mean that our products were no longer eligible for reimbursement under federal healthcare programs. Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of medical device and pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers; require pharmaceutical and medical device companies to comply with voluntary compliance standards issued by industry associations and the relevant compliance guidance promulgated by the U. S. federal government; and / or require disclosure to the government and / or public of financial interactions, so- called " sunshine laws ". The healthcare laws and regulations applicable to us, including those described above, contain ambiguous requirements and are subject to evolving interpretations and enforcement discretion. Manufacturers must adopt reasonable interpretations of requirements if there is ambiguity and those interpretations could be challenged. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil financial penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid. Any failure to comply with laws and regulations relating to reimbursement and healthcare goods and services could adversely

affect our reputation, business, financial condition and cash flows. International Laws Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EU member state legislation governing the advertising and promotion of medical devices. Sometimes the relevant rules are found in industry guidance rather than legislation — for example, relationships with healthcare professionals in the UK are governed by the code of Association of British ~~Healthcare~~ **HealthTech** Industries, or ABHI, and rules may limit or restrict the advertising and promotion of our products to the general public and impose limitations on our promotional activities with healthcare professionals. In the European Union the consequences for failing to comply with advertising and promotional laws might lead to reputational damage, fines, exclusions from public tenders and actions for damages from competitors for unfair competition. Laws with Extra- territorial Effect Many countries in which we operate have laws with extra- territorial effect — those laws apply to our operations outside the relevant country, to the extent they are breached. Examples of such laws include the Foreign Corrupt Practices Act, or the FCPA, the UK Bribery Act 2010 and the General Data Protection Regulation, or the GDPR. The extra- territorial effect of those laws affects our sales and marketing strategy, since in many countries healthcare professionals are officers of the state. This is particularly important in the context of bribery offenses, which in the UK and in the United States include the offense of bribing a foreign public official. Data Privacy and Security Laws We are, and in the future may become, subject to various U. S. federal and state as well as foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, governs the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to handle and protect, among other things, the privacy and security of protected health information, or PHI, in certain ways. HIPAA also requires business associates to enter into business associate agreements with covered entities and to safeguard a covered entity' s PHI against improper use and disclosure. HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate. These regulations also set forth certain rights that an individual may have with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. HIPAA security regulations set forth requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. The Health Information Technology for Economic and Clinical Health Act, among other things, provides certain health information security breach notification requirements. Under these laws, the covered entity must notify any individual whose PHI is breached as required under the breach notification rule. Although we believe that we currently are neither a " covered entity " nor a " business associate " directly under HIPAA, a business associate relationship may be imputed from facts and circumstances even in the absence of an actual business associate agreement. In addition, HIPAA may affect our interactions with customers who are covered entities or their business associates. The HIPAA privacy and security regulations establish a uniform federal " floor " and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their health and other personal information. States are increasingly regulating the privacy and security of individually identifiable information, including financial information and health information. For example, the California Consumer Privacy Act, or CCPA, gives California residents certain rights, including the right to ask covered companies to disclose the types of personal information collected and delete a consumer' s personal information, and imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities and limitations on covered companies' ability to sell personal information. These protections ~~will be~~ **have been** expanded by California Privacy Rights Act of 2020, or CPRA, ~~which will be operational in most key respects in 2023,~~ along with new privacy laws in Virginia, Colorado ~~, Utah~~ and ~~Connecticut~~ **several other states** . We expect additional federal and state legislative and regulatory efforts to regulate consumer privacy in the future. **Some states have also passed further protections focused on data protection for health information, including the Washington My Health My Data Act.** In the ~~European Economic Area, or~~ EEA, as well as in the United Kingdom, or the UK,- post- Brexit, we may be subject to laws relating to our collection, control, processing and other use of personal data, such as data relating to an identified or identifiable living individual. Following Brexit, the UK has substantively retained the same privacy rules as it had when a member of the European Union. We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EEA includes the GDPR, regarding the processing of personal data and the free movement of such data, which became applicable on May 25, 2018, the E- Privacy Directive 2002 / 58 / EC and national laws implementing or supplementing each of them. Each EU member state has transposed the requirements laid down by the E- Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. The GDPR was retained post- Brexit in the UK as the UK GDPR. In addition, many EEA member states have passed legislation addressing areas where the GDPR permits member states to derogate from the regulation' s requirements, thus leading to divergent requirements between member states in spite of the GDPR' s stated goal of creating a uniform privacy law for the entire EEA. The UK has done the same. We need to ensure compliance with the rules in each jurisdiction where we are established. Even if not established in the EEA (or the UK), we may otherwise be subject to local privacy laws in those regions. For example, we may be subject to the GDPR (or UK GDPR) even when processing personal data in connection with offering goods or services to persons located in the EEA (or UK) or monitoring the behavior of persons located in the EEA (or UK). GDPR requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a certain legal bases set forth in GDPR, and may only be processed in a manner consistent with those purposes. Processing of personal data also needs to be adequate, relevant, not excessive in relation to the purposes for which it is collected and secure. Personal data must not be kept for longer than

necessary for the purposes of collection. To the extent that we process, control or otherwise use sensitive data relating to living individuals (for example, patients' health or medical information, or genetic data or biometric data used for identification purposes, and other types of" special category data" listed in GDPR), more stringent rules may apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA (UK). In particular, in order to process such data, explicit consent to the processing (including any cross- border transfer) may be required from the data subject (being the person to whom the personal data relates), though in certain cases, and depending on the jurisdiction in which the data originate or are processed, such data may be processed absent explicit consent for purposes of medical diagnosis, public interest in the area of public health (including the safety and efficacy of medical devices) or scientific research. The same rules apply to us in the UK under the UK GDPR. The GDPR and UK GDPR also impose potentially onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and privacy policies / notices. They require data controllers to be transparent and disclose to data subjects in privacy notices (in a concise, intelligible and easily accessible form but at the same time at a sufficiently granular level) how their personal information is to be used, impose limitations on retention of information, encourage the use of pseudonymization techniques (i. e., key- coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non- compliance with the GDPR and the UK GDPR may be significant. The GDPR provides that EEA member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data (and other special category data), which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. EU GDPR (or UK GDPR) protected data must not be transferred outside of the EEA or UK, respectively, to a non- adequate country (i. e. a country that has not been recognized by the European Commission (in respect of the EU GDPR protected data) or the Secretary of State (in respect of the UK GDPR protected data) as providing an adequate level of protection for the transferred data), unless certain steps are taken to ensure an adequate level of protection. In practice, these extra steps would normally mean (i) entering into EU Standard Contractual Clauses (or, in case of the UK personal data, the UK Addendum to EU Standard Contractual Clauses or, alternatively, the IDTA i. e. the ICO' s International Data Transfer Agreement) or putting in place another data transfer mechanism, (ii) carrying out a transfer impact assessment and where necessary to protect the data, implementing supplementary measures. There are exemptions to these data transfer restrictions but these are interpreted narrowly. The July 2020 invalidation by the Court of Justice of the European Union of the EU- U. S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA (and, post-Brexit, the UK to the U. S., has led to increased scrutiny on data transfers from the EEA (and UK) to the U. S. generally and may increase our costs of compliance with data privacy legislation due to the requirement to enter into EU Standard Contractual Clauses (or, in case of the UK personal data, the UK Addendum to EU Standard Contractual Clauses or the IDTA) and further extra steps set out above. ~~.~~ In December 2022, the European Commission published its draft adequacy decision on the EU- US transfers of personal data- the new Data Privacy Framework, or EU- US DPF. Under the EU- US DPF, it will be possible to transfer EEA personal data freely to the US recipient that has self- certified under the EU- US DPF regime, although this may be challenged in the European Union Court of Justice by EU based privacy advocates. We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law. We depend on third parties in relation to provision of our services, a number of which process personal data on our behalf. With such providers we are legally required to enter into contractual arrangements which contain the minimum terms set out in the GDPR (and the UK GDPR), including to ensure that they process personal data only according to our instructions, and that they have adequate technical and organizational security measures in place. Where personal data is being transferred outside the EEA (or the UK), it must be done in compliance with applicable data export requirements. Any failure by us or third parties to comply with applicable data laws, could lead to a security or privacy breach, regulatory enforcement, or regulatory, reputational or financial harm. U. S. Healthcare Reform The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Additional healthcare reform efforts have sought to address certain issues related to the COVID- 19 pandemic. 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. We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. We cannot, however, predict the ultimate content, timing or effect of any healthcare reform legislation or action, or its impact on us, and healthcare reform could increase compliance costs and may adversely affect our future business, operations and financial results. Human Capital Management Our human capital strategy is comprehensive and leverages our work practices and collaborative culture. As of December 31, ~~2022~~ **2023** , we ~~had 212~~ **employed 584 people globally, most of whom were** full- time ~~employees, all of which are located in the United States other than five employees located in Europe. Except for certain European employees, none of our employees are represented by a labor union or are the subject of collective bargaining agreements, and we believe we have a strong relationship with our~~ employees. Our Culture We strive to foster an inclusive, engaging, and safe work environment where employees want to grow their careers. We promote understanding of our mission, vision, and values and create strong relationships with our employees through various engagement and career development initiatives. ~~We~~ **For example, we** hold quarterly Town Hall meetings with all employees to provide them with an open forum to ask questions, voice any concerns, and

provide input on our corporate goals and vision for the future. ~~We also host in- person events at our headquarters in Andover, Massachusetts, and invite employees from around the world to participate.~~ Diversity, Equity, and Inclusion: The keystone of our diversity strategy is mutual respect **and fostering a sense of belonging** – we want everyone to feel welcome and comfortable ~~at~~ **in** our organization **and feel that they are supported in growing their career** . Our workforce consists of individuals from countries all over the world, representing many different faiths, languages, backgrounds, and cultures. We believe that our diversity is one of our greatest strengths. We are committed to creating and maintaining an inclusive workplace in which all employees have an opportunity contribute to the success of the business. This commitment is embedded in our company policies and human capital management practices. ~~For example~~ **We have adopted policies to promote compliance with laws and regulations as well as to foster a respectful workplace for all employees. These policies include a code of business conduct and ethics** , ~~we offer~~ **an insider trading policy, a Regulation FD policy, a sexual harassment policy, a regulated fraternization policy, and a whistleblower policy. Along with an overview of the company, our culture and expectations, training on** ~~three~~ **these** ~~personal days to provide each~~ **policies is a key component of our** employee **onboarding process** ~~time away from work to use for any purpose, such as observing holidays that are meaningful to them~~ . Health and Safety: We are committed to maintaining compliance with laws and regulations surrounding the health and safety of our employees and strive to follow best practices in our operations. We require relevant employees to complete workplace safety training before performing any job duties that entail potential health hazards, such as trainings for employees who handle hazardous chemicals and biohazardous materials. Talent Attraction, Retention, and Development We continually seek exceptionally talented and dedicated people to join our team to help shape both our future and the future of transplant medicine. In recent years, the focus of our recruitment efforts has been centered on finding talent for the NOP and our engineering, manufacturing, and supply chain operations. **Since the launch of our aircraft operations in 2023, we are also seeking additional resources in the field of logistics and aviation, including logistics coordinators, pilots and aviation mechanics.** We aim to hire people with the right skill sets, growth mindset, and work ethic to drive business results and help us achieve our goals **. We provide relocation benefits to eligible employees whom we request to move in connection with their employment with the objective of attracting and deploying top talent** . Compensation and Benefits: We offer competitive compensation and benefits in an exciting, demanding, and fast- paced work environment. ~~Our~~ **We provide** employee benefits **to eligible employees to promote personal health and well- being and to provide certain financial security and protection upon retirement or in the event of death, disability or illness. These benefits to eligible employees** include a 401 (k) retirement plan with an employer matching contribution, health insurance (including medical, dental, and vision), life insurance, short- and long- term disability insurance, ~~reimbursement for fitness memberships~~ and **paid time off policies** ~~15 vacation days per year~~ . We offer an employee stock purchase plan to facilitate broad- based stock ownership by our employees. Career Development: We are proud to have a work environment that promotes continued development for our employees. Each employee is ~~assigned~~ **provided formal written feedback, at least annually, and together with his / her manager, develops** individual goals that are derived from our overall corporate and financial goals. Moreover, we collaborate with our employees to provide customized career development plans as well as general and targeted training curricula based on their roles ~~. We also provide skill development courses, manager training, and opportunities for managers and non- managers to develop their leadership skills~~ . Corporate Information and Organizational Transactions TransMedics Group, Inc., was incorporated in the Commonwealth of Massachusetts in October 2018 to facilitate our initial public offering, or IPO. TransMedics, Inc., an operating company and wholly- owned subsidiary of TransMedics Group, Inc., was incorporated in the State of Delaware in August 1998. Our principal executive offices are located at 200 Minuteman Road, Andover, Massachusetts 01810, and our telephone number at that address is (978) 552- 0900. Available Information Our Internet address is www. transmedics. com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10- K. Our Annual Report on Form 10- K, Quarterly Reports on Form 10- Q, Current Reports on Form 8- K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13 (a), 14, and 15 (d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the " Investors " portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, our filings with the SEC may be accessed through the SEC' s Electronic Data Gathering, Analysis and Retrieval system at http: / / www. sec. gov. All statements made in any of our securities filings, including all forward- looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law. Item 1A. Risk Factors. An investment in our common stock involves risks. **The** ~~You should consider carefully the~~ following risks and all of the other information contained in this Annual Report on Form 10- K **should be considered carefully** before investing in our common stock. The risks described below are those that we believe are the material risks that we face. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and ~~you~~ **investors** could lose all or part of ~~your~~ **their** investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. See " Forward- Looking Statements " in this Annual Report on Form 10- K. Risks Related to Our Financial Position and Need for Additional Capital We have incurred substantial losses since our inception and **have never generated net income on an annual basis** ~~anticipate that we will continue to incur losses in the future~~ . Since our inception, we have incurred significant operating losses. Our ability to generate revenue sufficient to achieve **sustained** profitability will depend on ~~successful commercialization~~ **the continued growth in customer utilization** of our OCS products **and services** . We generated revenue of $ **241. 6 million, $** 93. 5 million ~~,~~ **and** $ 30. 3 ~~million and $ 25. 6~~ million for the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , respectively, and incurred net losses of $ **25. 0 million, $** 36. 2 million ~~,~~ **and** $ 44. 2 ~~million and $ 28. 7~~ million for these same

years. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of $ ~~478~~ **503**. 7 million. To date, we have funded our operations primarily with proceeds from sales of equity, borrowings under loan agreements **, issuance of our 1. 50 % convertible senior notes due 2028, or our Notes,** and revenue from clinical trials and commercial sales of our OCS products **and services**. Our losses have resulted principally from costs incurred in connection with our research and development, clinical trials, manufacturing and commercialization activities, including the development of our **NOP** ~~National OCS Program~~. We expect ~~to~~ **our operating and capital expenditures will** continue to **increase** ~~incur net losses~~ for the foreseeable future as we focus on growing commercial sales of our products in both the U. S. and select non- U. S. markets, including **growing our NOP and** expanding our **NOP offerings to include transportation logistics services, including the acquisition of** ~~National~~ **additional** ~~OCS Program,~~ **aircraft to support aviation transportation;** growing our commercial team, which will pursue increasing commercial sales of our OCS products; scaling our manufacturing operations; continuing research and development for our next generation OCS products; and seeking regulatory clearance for new products and product enhancements, including new indications, in both the U. S. and select non- U. S. markets. The timing and amount of our operating and capital expenditures will depend on many factors, including: • the amount of ~~net~~ product revenue generated by sales of our OCS Consoles, OCS Perfusion Sets and OCS Solutions and other products that may be approved in the United States and select non- U. S. markets, revenue generated by our services, and ~~expansion~~ **growth** of the NOP; • the costs and expenses of expanding our U. S. and non- U. S. commercial infrastructure and our manufacturing operations; • the extent to which our OCS products are adopted by the transplant community; • the ability of our customers to obtain adequate reimbursement from third- party payors for procedures performed using the OCS products; • the costs incurred in our efforts to ~~expand~~ **operate and grow** our **NOP, including the costs and timing of growing our logistics capabilities, inclusive of acquiring** ~~National~~ **additional** ~~OCS Program~~ **aircraft for our aviation transportation services**; • the costs and timing of research and development of the next generation of OCS products; • the degree of success we experience in commercializing our OCS products for additional indications; • the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for the next generation of OCS products or for new indications for our OCS products; • the emergence of competing or complementary technologies; • the number and types of future products we develop and commercialize; • the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property- related claims; and • the level of our selling, general and administrative expenses. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Our existing and any future indebtedness could adversely affect our ability to operate our business. As of December 31, ~~2022~~ **2023**, our outstanding principal balance of long- term debt under our credit agreement with Canadian Imperial Bank of Commerce, or CIBC, was $ 60. 0 million, which we refer to as the CIBC Credit Agreement. ~~We could incur additional indebtedness in the future.~~ Our payment obligations under the CIBC Credit Agreement reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the CIBC Credit Agreement bears interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase substantially, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs. We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under or refinance our indebtedness under the CIBC Credit Agreement, which ~~matures~~ **is repayable in equal monthly installments starting in July 2026 until its maturity** in July 2027. Our obligations under the CIBC Credit Agreement are secured by substantially all of our assets and the assets of our wholly- owned material subsidiaries **, subject to certain exceptions**. The security interest granted over our assets could limit our ability to obtain additional debt financing. In addition, the CIBC Credit Agreement contains covenants requiring certain financial performance metrics that restrict our activities, including (x) a requirement to maintain a minimum liquidity amount of the greater of either (i) the consolidated adjusted EBITDA loss (or gain) for the trailing four month period (only if EBITDA is negative) and (ii) $ 10. 0 million, and (y) a requirement to maintain total net revenue of at least 75 % of the level set forth in the total revenue plan presented to CIBC. Failure to comply with the covenants in the CIBC Credit Agreement, including the financial covenants, could result in the acceleration of our obligations under the CIBC Credit Agreement, which are also subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to regulatory approvals and a material adverse change in our business, operations or other financial condition. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, CIBC may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. If such acceleration were to occur, it would materially and adversely affect our business, financial condition, operating results, cash flows and prospects. Our outstanding indebtedness ~~and any future indebtedness~~, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. See “ Item 7. Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Long- term Debt ” in this Annual Report on Form 10- K. **Servicing our 1. 50 % convertible senior notes due 2028 requires a significant amount of cash, and we may not have sufficient cash flow to pay our debt. In May 2023, we issued $ 460. 0 million aggregate principal amount of the Notes, pursuant to that certain indenture dated as of May 11, 2023, between us as issuer, and U. S. Bank Trust Company, National Association, as trustee. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to many factors, including, economic, financial, competitive and other, beyond our**

control. If our business does not generate cash flow from operations sufficient to service our debt and make necessary capital expenditures, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Notes, which mature in 2028, will depend on the capital markets and our financial condition at such times. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, and limit our flexibility in planning for and reacting to changes in our business. We may not have the ability to raise the funds necessary to repurchase the Notes as required upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes. Holders of the Notes will have the right to require us to repurchase their Notes for cash upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100 % of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then- existing indebtedness. We cannot guarantee that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change repurchase price in cash with respect to any Notes surrendered by holders for repurchase upon a fundamental change. In addition, restrictions under our then existing credit facilities or other indebtedness, if any, may not allow us to repurchase the Notes upon a fundamental change. Our failure to repurchase the Notes upon a fundamental change when required would result in an event of default with respect to the Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes. Capped call transactions entered into in connection with the Notes may impact the value of our common stock. In connection with the Notes, we entered into capped call transactions with certain financial institutions. The capped call transactions are expected to generally reduce the potential dilution upon conversion of the Notes into shares of our common stock. In connection with establishing their initial hedges of the capped call transactions, these financial institutions or their respective affiliates may have entered into various derivative transactions with respect to our common stock and / or purchased our common stock. The financial institutions, or their respective affiliates, may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes. This activity may have an impact on the value of our common stock. Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and may cause our results to fall short of expectations. Our financial results may fluctuate from quarter to quarter due to a number of factors, including the availability of donor organs for transplantation, which is unpredictable and could impact the volume of transplant procedures performed at transplant centers using the OCS and demand for our **NOP** ~~National OCS Program~~. Our revenue from sales may fluctuate significantly from quarter to quarter, and our future quarterly and annual expenses as a percentage of our revenue may be significantly different from those we have recorded in the past. **In addition, the timing of acquiring additional aircraft for our aviation transportation services is uncertain and the amount we incur for such acquisitions is likely to differ from quarter to quarter.** Our financial results in some quarters may fall below expectations. Comparing our financial results on a period- to- period basis may not be meaningful, and ~~you should not rely on our~~ past results ~~as~~ **may not be** an indication of our future performance. Because the timing of organ transplant procedures is generally unpredictable, we have not experienced seasonality in our business from quarter to quarter. Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to limitations. As of December 31, ~~2022~~ **2023**, we had federal net operating loss, or NOL, carryforwards of $ ~~378~~ **376**. ~~5~~ **4** million, which may be available to offset future taxable income, of which $ ~~209~~ **207**. ~~5~~ **4** million of the total net operating loss carryforwards expire at various dates beginning in ~~2023~~ **2024**, while the remaining $ 169. 0 million do not expire but are limited in their usage to an annual deduction equal to 80 % of annual taxable income. As of December 31, ~~2022~~ **2023**, we had state net operating loss carryforwards of $ ~~321~~ **328**. ~~2~~ **8** million, which may be available to offset future taxable income and expire at various dates beginning in 2030. As of December 31, ~~2022~~ **2023**, we also had U. S. federal and state research and development tax credit carryforwards of $ ~~9~~ **10**. ~~0~~ **7** million and $ ~~5~~ **6**. 5 million, respectively, which may be available to offset future tax liabilities. Our U. S. federal research and development tax credit carry forwards ~~began to~~ expire **beginning** ~~in 2023 and our state research and development tax credit carryforwards begin to expire~~ in 2024. A material portion of these NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change, " generally defined as a greater than 50 % change by value in its equity ownership over a three- year period, is subject to limitations on its ability to utilize its pre- change NOLs, its research and development credit carryforwards and its disallowed interest expense carryovers to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. Our NOLs and credits may also be impaired under state law. For these reasons, if we determine that an ownership change has occurred or in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers incurred prior to 2019. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above, we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U. S. federal or state taxable income necessary to utilize our NOL or credit carryforwards. Under the Tax Cuts and Jobs Act, or TCJA, NOLs arising in taxable years beginning after December 31, 2017 will not be subject to expiration. In addition, the

deduction for NOLs in any taxable year is limited to 80 % of annual taxable income in respect of NOLs generated during or after 2018. The TCJA also reduced the corporate income tax rate to 21 %, from a prior rate of 35 %. This may cause a reduction in the potential economic benefit of our NOLs and other available deferred tax assets. We may need to raise additional funding, which might not be available on favorable terms or at all. Raising additional capital may cause dilution to our shareholders. ~~Although we fund a portion of our operations from revenue from sales of our OCS products and services, we expect that we will need to finance our operations through a combination of equity offerings, debt financings and strategic alliances until~~ **Until** such time, if ever, that we can generate substantial revenue sufficient to achieve **sustained** profitability **, we may need to finance our operations through a combination of equity offerings, debt financings and strategic alliances** . We also may elect to raise additional funds ~~sooner~~ because we believe market conditions are attractive or as a risk mitigation measure. Additional capital might not be available when we need it, and our actual cash requirements might be greater than anticipated. If we require additional capital at a time when investment in our industry or in the marketplace in general is limited, we might not be able to raise funding on favorable terms, if at all. If we are not able to obtain financing on terms favorable to us, we may need to significantly delay, scale back or discontinue our development or commercialization activities, sell or license to third parties some or all of our assets or merge with another entity or may be forced to reduce or terminate our operations ~~any of which could result in a loss of all or part of your investment~~ . If we raise additional funds through the issuance of equity or convertible securities, the issuance of these securities could dilute ~~your~~ **shareholders'** percentage ownership in our company. Furthermore, newly issued securities may have rights, preferences or privileges senior to those of common shareholders. If we raise additional funds through additional debt financing, we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. The terms of any debt financing also could impose significant restrictions on our operations. Risks Related to Product Commercialization and Development Our long- term growth depends on our ability to expand access to the OCS through our **NOP** ~~National OCS Program~~ . We have developed **the NOP** ~~a National OCS Program~~ , an innovative turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS. We believe the **NOP** ~~National OCS Program~~ will continue to expand access and use of the OCS. However, we may not be successful in the continued development of our **NOP** ~~National OCS Program~~ , which will depend on recruiting **, training** and retaining qualified surgeons **and pilots** and establishing and maintaining effective coordination with transplant centers and regional Organ Procurement Organizations to locate donor organs and recipients. We may not be able to recruit **, train** and retain surgeons **, pilots** and other qualified personnel, including due to demand for their capabilities and competitive compensation offered by other employers. In order to recruit **, train** and retain such highly qualified employees, we also may need to increase the level, or change the form or composition, of the compensation that we pay to them, which would increase our expenses. In addition to our own surgical and clinical personnel, we utilize a network with a limited number of partners for organ retrieval, organ preservation and transportation services offered through our **NOP** ~~National OCS Program~~ . If any of these relationships are interrupted or terminated, or if one or more partners are unable or unwilling to fulfill their obligations for any reason, **NOP** ~~National OCS Program~~ services to our customers may be interrupted. We also may not be able to identify or negotiate with additional partners on terms that are commercially reasonable to us. The interruption or failure to retain or replace partners for our **NOP** ~~National OCS Program~~ would negatively impact our operations and financial results. Furthermore, the expenses incurred by us ~~for sales of OCS products~~ to customers who participate in our **NOP** ~~National OCS Program~~ are ~~typically higher than expenses for sales~~ **dependent on many different market dynamics, including the cost** of **fuel and** ~~OCS products to our~~ other **transportation costs** ~~customers and as we seek to increase sales of our OCS products through our National OCS Program our gross margin may decline~~ . Additional expenses incurred by our **NOP** ~~National OCS Program include the cost of transportation and increases in the cost of fuel and other transportation costs would impact our expenses related to operating the National OCS Program, which~~ could adversely affect our business **, gross margin** , financial condition, operating results, cash flows and prospects. We will need to increase our manufacturing and sterilization capacity in the future and may encounter problems at our manufacturing facility or otherwise. In order to manufacture the OCS in quantities sufficient to meet our anticipated commercial opportunity, we will need to continue to increase our manufacturing capabilities ~~, including operationalizing our expanded clean room at our Andover facility,~~ and retain third parties to sterilize our products. We may encounter technical challenges to increasing the scale at which we manufacture the OCS, including with respect to material procurement and quality control and assurance. An increase in production could make it more difficult for us to comply with quality system regulations or other applicable requirements that are currently enforced by the FDA and other regulatory authorities, or that may be introduced in the future, in both the United States and in other countries. Commercial scale production of the OCS on a continuing basis also will require us to continue to hire and retain additional management and technical personnel who have the necessary manufacturing experience and skills. We might not successfully identify, hire or retain qualified personnel on a timely basis or at all. To maintain quality of our OCS, we may not be able to scale production of our OCS products at a rate that meets customer demand for our products. Our inability to increase the scale of our manufacturing of the OCS could impair our ability to generate revenue and adversely affect market acceptance of our product. In addition, all of our manufacturing operations are conducted at a single facility in Andover, Massachusetts. Any interruption in operations at this location ~~, or delays in operationalizing our expanded clean room facility,~~ could result in our inability to satisfy product demand. Despite our efforts to safeguard this facility, including acquiring insurance on commercially reasonable terms, adopting environmental health and safety protocols and utilizing off- site storage of computer data, a number of factors could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses, including: • operating restrictions, partial suspension or total shutdown of production imposed by regulatory authorities; • equipment malfunctions or failures; • technology malfunctions; • work stoppages; • damage to or destruction of the facility due to natural disasters or other events; or • regional or local power shortages. Our insurance may not cover our losses in

any particular case, or insurance may not be available on commercially reasonable terms to cover certain of these catastrophic events. In addition, regardless of the level of insurance coverage, damage to our facilities or any disruption that impedes our ability to manufacture the OCS in a timely manner could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. We rely on third- party vendors to sterilize our disposable sets prior to sale. If vendors are unable to sterilize our products, whether due to capacity, availability of materials for sterilization, regulatory or other constraints, including federal and state regulations on the use of ethylene oxide used in the sterilization process, we will not be able to sell products until we can retain an alternative vendor to sterilize the products. We may be unable to transition to alternative methods of sterilization in a timely or cost- effective manner or at all, which could harm our business and results of operations. Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory. We seek to maintain sufficient levels of inventory, including our OCS Perfusion Sets, in order to protect ourselves from supply interruptions and to support the demand from customers, but keep limited components, sub- assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including the rate of transplantations, product recalls, failure to accurately manage our commercial strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, changes to hospital capacity, staffing, procedure and protocol changes, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. We also maintain inventory reserves at regional locations for distribution through our **NOP** ~~National OCS Program~~. If we are not able to maintain sufficient inventory at these locations, or if we are not able to accurately predict the regional demand for our OCS products, we will incur additional costs to transport inventory to our regional locations, including rebalancing inventory amongst regional locations, and we may not be able to grow our commercial sales as anticipated. Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write- downs or write- offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub- assemblies and materials to meet our requirements and our manufacturing may be affected by the impact ~~of COVID- 19, general impacts~~ of inflation and labor shortages on our suppliers, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub- assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations. We aim to maintain strategic reserves of our OCS Perfusion Sets, but if we are not able to manufacture and assemble OCS Perfusion Sets at a rate that will allow us to maintain these reserves, then we will be required to rely on alternative strategies to deliver OCS Perfusion Sets in a timely manner, which may impact our expenses and results of operations. We depend heavily on the success of the OCS and it ~~achieving~~ **gaining additional** market acceptance. If we are unable to **continue to** successfully commercialize the OCS, our business may fail. We have invested **substantial** ~~all of our~~ efforts and financial resources in the development of the OCS, educating surgeons, transplant centers, Organ Procurement Organizations and private and public payors of the benefits of the OCS, providing services related to the OCS and launching our **NOP** ~~National OCS Program~~. Although we have received PMAs from the FDA for each of our three OCS products, we might not **be able to continue to** successfully commercialize the OCS for these approved indications or obtain approvals for additional indications or in additional jurisdictions on our planned timing or at all. Our ability to generate product revenue and become profitable depends primarily on sales of OCS Perfusion Sets and OCS Solutions, which we refer to collectively as disposable sets. Our assumptions regarding demographic trends, donor organ availability and the use of transplantation as a treatment for end- stage organ failure may prove to be incorrect. We expect that we will need to continue to demonstrate to surgeons, transplant center program directors, Organ Procurement Organizations and private and public payors that the OCS potentially results in some or all of the following: improvements in post- transplant clinical outcomes, increases in the utilization of donor organs, expansion of the pool of potential donors and reduction in the total cost of care as compared to available alternatives. Surgeons, transplant centers and private and public payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. The cost of the OCS significantly exceeds the cost of cold storage preservation. In addition, our international customers and some U. S. customers use a direct acquisition model pursuant to which transplant centers train their own teams for retrieval and organ management using the OCS rather than utilizing our **NOP** ~~National OCS Program~~. Surgeons may not be willing to undergo training to use the OCS, may decide the OCS is too complex to adopt without appropriate training and may choose not to use the OCS, which may limit the adoption of the OCS under the direct acquisition model. Based on these and other factors, transplant center program directors, Organ Procurement Organizations and private and public payors may decide that the benefits of the OCS do not outweigh its costs. In addition, adoption of the OCS may be constrained by the capacity of individual transplant centers to perform transplants due to factors such as the number of its surgeons trained on the use of the OCS. As a result, demand for the OCS could be materially lower than we expect it to be, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects. We must continue to educate surgeons, transplant centers and private and public payors and demonstrate the merits of the OCS compared with cold storage or new competing technologies. Directors of transplant programs are key decision- makers in the adoption of novel medical devices used in organ transplantation. An important part of our commercialization efforts is to educate transplant center program directors and other

surgeons on the relative merits of the OCS. Our success depends, in large part, on effectively marketing and educating program directors and other surgeons about the benefits of the OCS and our **NOP** ~~National OCS Program~~. Acceptance of the OCS also depends on educating program directors, other surgeons and private and public payors as to the distinctive characteristics, perceived medical and economic benefits, safety, ease of use and cost- effectiveness of the OCS and our **NOP** ~~National OCS Program~~. If program directors, other surgeons and private and public payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for our products and **NOP** ~~National OCS Program~~ Services. Currently, most universal national healthcare systems outside of the United States do not reimburse transplant centers for the use of the OCS and reimbursement in international markets may require us to undertake additional clinical studies. In addition, the long- term effects of our OCS following transplantation are not yet known. Certain surgeons, transplant centers and private and public payors may prefer to see longer- term safety and efficacy data than we have produced. We cannot provide assurance that any data that we or others may generate in the future will be consistent with that observed in our existing clinical studies. In addition, as the **NOP** ~~National OCS Program~~ expands access to the OCS, transplant surgeons may increasingly rely on clinical data regarding the organ provided to them by our clinical specialists and surgeons. We are responsible for the clinical data regarding the organ that is provided to transplant surgeons who participate in the **NOP** ~~National OCS Program~~. Our long- term growth depends on our ability to improve the OCS platform, including by **developing the next generation of our products or** expanding into new indications ~~and developing the next generation of our products~~. Our business plan contemplates that we will continue to improve the OCS platform, including by **developing the next generation of our products or** expanding into additional organs ~~and developing the next generation of our products~~. Developing such new or modified products is expensive and time- consuming and diverts management' s attention away from current operations. The success of any new product offering or product enhancements to our OCS platform will depend on several factors, including our ability to: • properly identify and anticipate surgeon and patient needs; • develop and introduce new products and product modifications in a timely manner; • avoid infringing upon, misappropriating or otherwise violating the intellectual property rights of third parties; • demonstrate the safety and efficacy of new products and product modifications; • obtain necessary regulatory clearances or approvals; • comply with regulations regarding the marketing of new products or product modifications; • provide adequate training to potential users of our products; • receive adequate coverage and reimbursement for procedures performed with our products; and • develop an effective commercialization effort. If we are not successful in expanding our indications and developing the next generation of our products, our ability to increase our revenue may be impaired, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. We **may not fully realize the anticipated benefits of our completed or future acquisitions, joint ventures, and strategic investments, such transactions may expose us to additional risks. On August 2, 2023, we acquired certain assets related to lung and heart perfusion technology from Bridge to Life Ltd. and its subsidiary Tevosol, Inc., or together Bridge to Life. In addition, on August 16, 2023, we acquired Summit, an aviation business. We** have ~~limited experience in directly marketing~~ **separately acquired 13 fixed- wing aircraft,** and ~~selling~~ **intend to acquire additional fixed- wing aircraft, that will be operated as part of our NOP. Utilization of these acquired assets and integration of Summit, may be complex, costly and time consuming and we may face unanticipated issues, expenses and liabilities. We may not successfully** ~~our~~ **or** ~~products~~ **profitably utilize newly acquired assets or integrate**, **operate, maintain** and **manage any newly acquired operations or employees. Further development of the assets we acquired from Bridge to Life, or the Bridge to Life Assets, will require extensive clinical development, management of nonclinical, clinical and manufacturing activities. In addition, we may decide that only certain of the acquired technology is useful for the next generation of the OCS, or that integration of the acquired technology is not feasible or is too costly. We also may face challenges integrating Summit into our organization. We have never provided aviation transportation services prior to the acquisition and will depend on the management team of Summit for the successful operation and integration into our NOP services offering. Even** if we are ~~unable~~ **able** to **utilize the Bridge to Life Assets and integrate Summit or any other acquired assets or businesses** successfully ~~expand our sales infrastructure and adequately address our customers' needs~~, ~~it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability. We have limited experience in directly marketing and selling our products in the United States. Our operating results are dependent upon our sales and marketing efforts. If we fail to adequately promote and market our products, our sales may not grow or could significantly decrease. We believe it is necessary to utilize a sales force that incorporates a specialized group consisting of sales representatives and clinical specialists who have experience with products to support our customers' needs. Competition for sales representatives and marketing employees is intense and we may be unable to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and~~ we may not **realize** ~~generate sufficient revenue to achieve or sustain profitability. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled surgeons, sales representatives and clinical specialists, and ensuring our sales program offerings satisfy~~ the ~~needs~~ **expected benefits** of ~~our customers~~ **the transactions**. ~~New hires require training~~ **These are the Company' s first acquisitions,** and ~~take time to achieve full productivity. If~~ we ~~fail to train new hires adequately, if we experience high turnover in our sales force in the future, or if our sales program offerings do not satisfy the needs of our customers, new hires~~ may ~~not become as productive as~~ **need to invest in additional business processes and systems to support the Summit integration or to utilize the Bridge to Life Assets. Such additional costs may offset the financial benefits that** may be ~~necessary~~ **realized from the acquisitions. We also may suffer the loss of key employees and strategic partners of Summit and it may be difficult** to ~~maintain~~ **implement** ~~or~~ **our corporate culture. There also may be increased risk due to integrating financial reporting and internal control systems of Summit. We may review additional acquisition, joint ventures and strategic investment opportunities to expand our current product offerings,** increase **the**

size and geographic scope of our operations ~~our~~ **or** ~~sales to expand our current product offerings,increase the size and geographic scope of our operations or~~ otherwise offer growth and operating efficiency opportunities.There can be no assurance that we will be able to identify suitable candidates or consummate ~~these~~ **future** transactions on favorable terms.If required,the financing for ~~these~~ **future** transactions could result in an increase in our indebtedness,dilute the interests of our shareholders or both.The purchase price for some acquisitions or joint ventures interests may include additional amounts to be paid in cash in the future,a portion of which may be contingent on the achievement of certain future operating results of the acquired business.If the performance of any such acquired business or joint venture exceeds such operating results,then we may incur additional charges and be required to pay additional amounts.Our failure to successfully **utilize any acquired assets,** complete the integration of any acquired business ~~or to~~ **,including retention of key employees,customers and strategic partners,** achieve the long- term plan for such **assets or** ~~business~~ **businesses** ,as well as any other adverse consequences associated with our acquisition and investment activities,could have an adverse effect on our business.Any acquisition may also disrupt our ongoing business,divert resources,increase our expenses,and distract our management from our ongoing operations . We depend on a limited number of customers for a significant portion of our revenue and the loss of, or a significant shortfall in demand from, these customers could have a material adverse effect on our financial condition and operating results. We generate a significant amount of our revenue from a limited number of customers. ~~For the year ended December 31, 2022, the Mayo Clinic Hospital- Phoenix accounted for 14 % of our revenue.~~ However, ~~this customer or~~ **our** ~~any of our other~~ customers may not continue to utilize our products **or services** at current levels, pricing, or at all, and our revenue could fluctuate significantly due to changes in economic conditions, the use of other methods for organ preservation, such as cold storage, or the loss of, reduction of business with, or less favorable terms with any of our largest customers. Our future success will depend upon the timing and volume of business from our largest customers and the financial and operational success of these customers. If we were to lose **a** ~~one of our~~ key ~~customers~~ **customer** or have a key customer significantly reduce ~~its~~ **their** volume of business with us, our revenue may be materially reduced, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects. ~~Revenue from~~ **Substantially all of our U. S.** customers ~~who~~ **now** ~~participated~~ **participate** in our **NOP and our** ~~National OCS Program accounted for approximately 89 % of total revenue from customers in the United States for the year ended December 31, 2022. Our~~ success will depend on our ability to maintain the function and efficiency, while increasing capacity and capability, of **the NOP** ~~our National OCS Program~~ . If we are unable to deliver OCS products to customers through their participation in the **NOP** ~~National OCS Program~~ , our revenue ~~may~~ **would** be materially reduced, which would materially and adversely effect our business, financial condition, operating results, cash flows and prospects. We depend on single- source suppliers and, in a few cases, sole- source suppliers for many of the components used in the OCS. We rely on single- source suppliers and, in a few cases, sole- source suppliers for many of the components used in the OCS. For example, each of Fresenius Kabi Austria GmbH and Fresenius Kabi AB, which we refer to collectively as Fresenius, is our single- source supplier of OCS Solutions for the OCS Lung and the OCS Heart, respectively. While we have manufacturing and supply agreements with certain of our suppliers, for most of our suppliers, we place purchase orders on an as- needed basis. Our suppliers could discontinue the manufacturing or supply of these components at any time. We do not carry a significant inventory of some of these components. Our suppliers may not be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us. In addition, if these suppliers are unable to deliver components to us, whether due to a labor shortage, slow down or stoppage, or for any other reason, we would be required to seek alternative suppliers. We might not be able to identify and qualify additional or replacement suppliers for any of these components quickly or at all or without incurring significant additional costs. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. We also may choose to establish our own manufacturing process of certain components and we may not be successful in doing so. For example, we will need to seek FDA approval for any component design we choose to manufacture, which may not be granted in a reasonable time, or at all. In addition, the components we design may not be successful or may not provide a functional or economic benefit compared to similar components manufactured by third parties. If we choose to establish our own manufacturing process of components of the OCS, we may be required to procure additional raw materials for such processes, which may not be available. We may also face regulatory delays or be required to seek additional regulatory clearances or approvals if we experience any delay or deficiency in the quality of products obtained from suppliers or if we have to replace our suppliers. In addition, many of the components used in the OCS are specifically designed for use in the OCS, which means that off- the- shelf components may not be available as substitutes. Establishing additional or replacement suppliers for any of these materials or components, if required, or any supply interruption from our suppliers, could limit our ability to manufacture our products, result in production delays and increased costs and adversely affect our ability to deliver products to our customers on a timely basis. Our inability to obtain sufficient quantities of components for the OCS also could adversely affect development of the next generation of the OCS. If we are not able to identify alternate sources of supply for the components, we might have to modify our product to use substitute components, which could lead to additional regulatory obligations that could impact our marketing ability, cause delays in shipments, increase design and manufacturing costs and increase prices for our products. Any such modified product might not be as effective as the predecessor product or might not gain market acceptance. This could lead to customer dissatisfaction and damage to our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. ~~We~~ **In addition to our aviation transportation services, we also** depend on third parties to transport donor organs and medical personnel for our **NOP** ~~National OCS Program~~ , and limited availability of, or increases in the cost of, transportation could limit our ability to ~~expand~~ **grow** or operate **the NOP** ~~our National OCS Program~~ . ~~Our~~ **In addition to our aviation transportation services, our** NOP depends on the use of a third- party network of private aircraft to transport medical personnel to retrieve donor organs and deliver donor organs to patients for transplantation. Reliance

on private aircraft is subject to various risks, including those associated with change in fuel prices, work stoppages and weather-related operating hazards. In particular, private aircraft are occasionally in high demand and / or subject to price fluctuations based on market conditions. Further, availability is constrained by a limited number of private aircraft available in the United States and a limited number of qualified pilots. As a result, third - party private aircraft providers may not be able to prioritize our use of their services. If we are unable to obtain flight services for our NOP when needed, we may be unable to utilize our NOP to satisfy demand. We also may be required to seek alternative and, potentially more costly, flight services. ~~These flight costs represent a significant part of the cost structure for our NOP, and although~~ **Although** the cost of flights is paid by our customers, a substantial increase in the cost of flight services, due to prolonged increases in fuel prices, lack of availability of aircraft or otherwise, may require us to incur additional costs to identify and obtain alternative flights or rebalance our inventory by shipping products to locations for which flight costs are less expensive or from which flights are more readily available, and customers may be unwilling or unable to incur higher costs of flights and therefore forgo use of our services and products for the retrieval of donor organs despite availability. Further, the capacity of our NOP is limited by the number of aircraft and pilots available for our use and as we continue to ~~expand~~ **grow** our NOP, we will be required to obtain access to a greater number of available aircraft and pilots. We may not be able to achieve or maintain satisfactory pricing and margins for our products **or services** . Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for OCS ~~Products~~ **products or services** could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products **or services** , our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations. Price increases of the components used to manufacture our products and supply shortages could adversely affect our business and operating results. The supply of raw materials to our component parts suppliers could be interrupted for a variety of reasons, including availability and pricing. We may experience supply chain disruptions due to general impacts of inflation and labor shortages and these disruptions to the supply chain could adversely affect our ability to meet commitments to customers. Significant price increases could adversely affect our results of operations and operating margins. In particular, inflation, changes in trade policies, the imposition of duties and tariffs and public health crises (such as the COVID- 19 pandemic) could adversely impact the price or availability of raw materials and the components of our products. We may not be able to pass along increased component part prices to customers in the form of price increases or our ability to do so could be delayed. Consequently, our results of operations and financial condition may be adversely affected. Our failure to compete effectively will harm our business and operating results. A broad range of medical device, pharmaceutical and biotechnology companies offer products, procedures and therapies that have the potential to limit the demand for organ transplantation. Companies within this group vary depending on the type of organ. New therapies for COPD, which includes emphysema and chronic bronchitis, could limit the demand for lung transplants. Alternative products, procedures and therapies including ventricular assist devices, cardiac rhythm management products, total artificial hearts, and drug therapies for the heart and surgical procedures could limit demand for heart transplants. Improved treatments for chronic diseases or conditions affecting the liver as well as efforts to develop artificial livers could limit the need for liver transplants. If demand for organ transplants decreases, sales of the OCS and its components will suffer. Other companies may develop technologies and products that result in improved patient outcomes or are safer, easier to use, less expensive or more readily accepted than the OCS. These products or technologies could make the OCS obsolete or noncompetitive and reduce demand for our OCS products. Many of these providers of alternative products, procedures and therapies have greater name recognition, significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and clearances and marketing and selling products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Third parties may also compete with us in recruiting and retaining qualified medical, engineering and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our products or development programs or otherwise advantageous to our business. Our failure to compete effectively will harm our business and operating results. The clinical trial process **that may be** required to obtain future regulatory approvals is lengthy and expensive, with uncertain outcomes. Clinical trials are necessary to support PMA applications and may be necessary to support future PMA supplements for modified versions of our marketed device products. Conducting clinical trials is a complex and expensive process, can take many years and outcomes are inherently uncertain. For the development of the next generation of OCS products or the development of OCS products for additional organs, we may incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the product tested will ever generate revenue sufficient to cover the costs of trials. 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. Successful results in early studies do not assure positive results in subsequent clinical trials. The data we collect from our preclinical studies and clinical trials may not be sufficient to support FDA or other regulatory clearance or approval. Additionally, the FDA may disagree with our interpretation of the data from our studies and trials. The FDA may conclude that the clinical trial design, conduct or results are inadequate to prove safety or effectiveness, and the FDA may require us to undertake expensive and lengthy additional trials, which may delay clearance or approval of products. Clinical trials often require enrollment of large numbers of subjects, who may be difficult to identify, recruit and maintain as participants in the

clinical trial. As a condition to our PMA approvals, we are required to conduct post- market studies. For example, we have post-approval registries ongoing for all three of our organ products, including the OCS Lung Thoracic Organ Perfusion Registry, or TOP Registry, the OCS Heart Perfusion Registry, or OHP, and the OCS Liver Perfusion Registry, or OLP. Adverse outcomes in post- approval studies can result in withdrawal of approval of a PMA or restrictions on the approval. We will need to conduct additional clinical studies to support use of the OCS in, and development of OCS products for, new organs, and potentially for commercialization of our products in additional foreign jurisdictions. Clinical trials in organ transplant are difficult to design and implement, take substantial time to conduct and are expensive. The results of clinical trials are inherently uncertain. The initiation and completion of any studies may be prevented, delayed or halted for numerous reasons. The following could adversely affect the costs, timing or successful completion of any clinical trial: • we have been required and, prior to collecting clinical data in the future to support new PMA applications, may be required again to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials, and the FDA may reject our IDE application and notify us that we may not begin investigational trials; • regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials; • regulators and / or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site; • we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different 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 or sterilizing our products, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all; • we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks; • we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and / or regulatory authorities for re- examination; • regulators, IRBs or other reviewing bodies may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements; • the cost of clinical trials may be greater than we anticipate; • we may be unable to recruit a sufficient number of clinical trial sites; • regulators ~~, IRBs~~ or other reviewing bodies may fail to **accept as satisfactory, fail to** approve **,** or subsequently find fault with our manufacturing processes or facilities of third- party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; • approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and • our current or future products may have undesirable side effects or other unexpected characteristics. Failure can occur at any stage of clinical testing. For example, our clinical studies may produce negative or inconclusive results, and, in the future, we may decide, or regulators may require us, to conduct clinical and non- clinical testing in addition to those we have planned. After submission of our PMA applications for OCS Lung and OCS Heart, the FDA requested certain additional clinical analyses, technical information and clarifications as part of the agency' s normal review process. The FDA ultimately approved both PMAs. The FDA could ask us to conduct additional clinical trials or submit additional evidence to support PMA applications in the future. Our failure to adequately demonstrate the safety and effectiveness of any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that product or indication for use. Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require marketing authorization from regulatory authorities in those countries. Authorization 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 materially and adversely affect our business, financial condition, operating results, cash flows and prospects. Risks Related to Our **Logistics** Operations **Prior to our acquisitions to facilitate our aircraft operations, we had no experience operating aircraft ourselves, and we may not be able to achieve the anticipated benefits of our acquisitions or further expansion of our aircraft operations. Prior to our acquisitions to facilitate our aircraft operations, we had no experience operating aircraft ourselves, and we depend on the management team of Summit and additional employees we may hire for the successful operation of aviation transportation services and the integration into our NOP services offering. The management teams must work together to comply with applicable laws and regulations and to manage our growing NOP logistics network. The operation of aircraft is a highly regulated activity and one that involves unique risks, including those described above, which we have not needed to manage previously. We may not successfully manage these risks or profitably utilize, integrate, operate, maintain and manage our newly acquired aircraft, employees and other aircraft operations. If we fail to retain the existing management of Summit, or if we fail to successfully manage our aircraft operations or growing logistics network, our ability to realize the anticipated benefits of the acquisition of Summit or expansion of our NOP may be adversely affected. The operation of aircraft is subject to various risks, and failure to maintain ~~and -~~ an acceptable safety record may have an adverse impact on our ability to obtain and retain customers. The operation of aircraft is subject to various risks, including catastrophic disasters, crashes, mechanical failures and collisions, which may result in loss of life, personal injury and / or damage to property, plant and equipment. We may experience accidents in the future. These risks could endanger the safety of our personnel, third- parties, equipment, viability of donor organs and other property (both ours and that of third- parties), as well as**

the environment. If any of these events were to occur, we could experience loss of revenue, termination of customer contracts, higher insurance rates, litigation, regulatory investigations and enforcement actions (including potential grounding of our fleet and suspension or revocation of our operating authorities) and damage to our reputation and customer relationships. In addition, to the extent an accident occurs with an aircraft we operate or charter, we could be held liable for resulting damages, which may involve claims from injured passengers, and survivors of deceased passengers and property owners. The amount of our insurance coverage may not be adequate to cover such losses, or we may be forced to bear substantial losses from such events, regardless of our insurance coverage. Moreover, any aircraft accident or incident, even if fully insured, and whether involving us or other private aircraft operators, could create a public perception that we are less safe or reliable than other private aircraft operators, which could cause our customers to lose confidence in us. We incur considerable costs to maintain the quality of (i) our safety program, (ii) our training programs and (iii) our fleet of aircraft. These costs may increase. If we are unable to maintain an acceptable safety record, we may not be able to retain existing customers and employees or attract new customers and employees, which could have a material adverse effect on our business, financial condition and results of operations. Failure to comply with regulatory requirements related to the maintenance of our aircraft and associated operations may result in enforcement actions, including revocation or suspension of our operating authorities in the United States. Significant reliance on aircraft manufactured by a single company and spare parts poses risks to our business and prospects. As part of our services offered under our NOP, we have acquired a fleet of fixed- wing aircraft. All of the aircraft we currently operate are variants of a single model produced by a single manufacturer. Parts and services from this manufacturer are subject to their product and workmanship warranties and capacity to service aircraft. If this manufacturer fails to adequately fulfill its obligations towards us or experiences interruptions or disruptions in production or provision of services due to, for example, bankruptcy, natural disasters, labor strikes or disruption of its supply chain we may experience a significant delay in the delivery of or fail to receive previously ordered parts, which would adversely affect our revenue and results of operations and could jeopardize our ability to meet the demands of our customers. Although we could choose to operate aircraft of other manufacturers or increase our reliance on third- party operators, such a change would involve substantial expense to us and could disrupt our business activities. We rely on Pratt & Whitney aircraft engines to power our owned aircraft, and we may enter into program agreements covering certain of our aircraft related to engine maintenance and overhauls for certain aircraft in our fleet. If Pratt & Whitney fails to adequately fulfill its obligations towards us or experiences interruptions or disruptions in production or provision of parts or services due to, for example, bankruptcy, natural disasters, labor strikes or disruption of its supply chain, we may experience a significant delay in the delivery of or fail to receive previously ordered aircraft engines and parts, which could result in grounded aircraft. These disruptions would adversely affect our revenue and profitability and could jeopardize our ability to meet the demands of our customers. In addition, if we fail to meet our obligations or are otherwise in default under the program agreements, our access to aircraft engines and parts may become limited, which could adversely impact our business, operations, cash flow, financial condition and liquidity. The Federal Aviation Administration, or FAA, could suspend or restrict the use of our aircraft in the event of actual or perceived mechanical problems or safety issues while it conducts its own investigation, whether involving our aircraft or another operator' s aircraft. The availability of pilots to the private aviation industries is limited and may negatively affect our operations and financial condition. Increases in our labor costs adversely affect our business, results of operations and financial condition. Our pilots are subject to stringent pilot qualification (including medical certification) and crew member flight training standards, or FAA qualification standards, which among other things require minimum flight hours for pilots, mandate strict rules to minimize pilot fatigue and require periodic recertification. These requirements limit the availability of qualified pilot candidates and increase pilot salaries and related labor costs, which increases our operating expenses. Such requirements also impact pilot scheduling, work hours and the number of pilots required to be employed for our operations. Further, in recent years, the airline industry has experienced significant volatility in pilot attrition, including volatility resulting from pilot wage and bonus increases at other industry participants, the growth of air cargo, additional charter operations and airlines, and more pilots reaching retirement age. If our attrition rates are higher than our ability to hire and retain replacement pilots, our operations and financial results would be adversely affected. In addition, our operations and financial condition may be negatively impacted if we are unable to train pilots in a timely manner. Due to an industry- wide shortage of qualified pilots, driven by the flight hours requirements under the FAA qualification standards, including any special requirements related to certain types of aircraft, and attrition resulting from the hiring needs of other industry participants, pilot training timelines have significantly increased and stressed the availability of flight simulators, instructors and related training equipment. The training of our pilots may not be accomplished in a cost- efficient manner or in a manner timely enough to support our operational needs. Due to the nature of our NOP services offering, which may require flight routes to various locations across the United States and often on short notice, we may not have access to a qualified pilot at the departure location. We may rely on commercial airlines to fly our pilots to the departure location. An inability to have pilots located in departure locations when necessary may cause us to delay or cancel a flight and could adversely affect our reputation, business, results of operation and financial condition. We are exposed to operational disruptions due to maintenance and third- party services. Our aircraft fleet requires regular maintenance work, which may cause operational disruption. Failure to perform timely maintenance and repairs results in aircraft being underutilized which could have an adverse impact on our business, financial condition and results of operations. On occasion, airframe manufacturers and / or regulatory authorities require mandatory or recommended modifications across a particular fleet which may ground a particular type of aircraft. This may cause operational disruption to, and impose significant costs on us. Furthermore, our

operations in remote locations, where delivery of components and parts or transportation of maintenance personnel could take a significant period of time, could result in delays in our ability to maintain and repair our aircraft. Any such delays may pose a risk to our business, financial condition and results of operations. Moreover, as our aircraft base increases and our fleet ages, our maintenance costs could potentially increase and we may be unable to manage the composition of our fleet in a manner that reduces costs due to the availability and prices for replacement aircraft and parts. We rely on third- party service providers to perform functions integral to our operations, including ground handling, landing fees, fueling, maintenance, and other services. Disruptions could occur and increase our operating costs or ability to meet customer demands. Significant increases in aviation fuel costs could have a material adverse effect on our business, financial condition and results of operations. Fuel is essential to the operation of our aircraft and to our ability to carry out our aircraft operations. Fuel costs are a key component of our operating expenses for our aircraft operations. A significant increase in fuel costs may impact our flight activity and otherwise negatively impact our revenue, operating expenses and results of operations. In addition, potential increased environmental regulations that might require new fuel sources (e. g., sustainable aviation fuel) could lead to increased costs. Our insurance may become too difficult or expensive to obtain. If we are unable to maintain sufficient insurance coverage, it may materially and adversely impact our results of operations and financial position. Hazards are inherent in the operation of aircraft and may result in loss of life and property, potentially exposing us to substantial liability claims arising from the operation of aircraft. We carry insurance customary for the operation of aircraft. Insurance underwriters are required by various federal and state regulations to maintain minimum levels of reserves for known and expected claims. However, underwriters may not have adequate reserves to fund existing and future claims. The number of accidents, as well as the number of insured losses within the aviation and aerospace industries, and the impact of general economic conditions on underwriters may result in increases in premiums above the rate of inflation. To the extent that our existing insurance carriers are unable or unwilling to provide us with sufficient insurance coverage, and if insurance coverage is not available from another source (for example, a government entity), our insurance costs may increase and may result in our being in breach of regulatory requirements or contractual arrangements requiring that specific insurance be maintained, which may have a material adverse effect on our business, financial condition and results of operations. The operation of aircraft is often affected by factors beyond our control including: air traffic congestion at airports; air traffic control inefficiencies; increased and changing security measures; changing regulatory and governmental requirements; new or changing travel- related taxes; any of which could have a material adverse effect on our business, results of operations and financial condition. Our aircraft operations are affected by factors beyond our control, including air traffic congestion at airports, air traffic control inefficiencies and staffing shortages, increased and changing security measures, changing regulatory and governmental requirements, and new or changing travel- related taxes. Factors that cause flight delays could prevent us from effectively transporting organs in a timely manner, which could have a material adverse effect on our business, results of operations and financial condition. In the United States, the federal government singularly controls all U. S. airspace, and aviation operators are completely dependent on the FAA to operate that airspace in a safe, efficient and affordable manner. The air traffic control system, which is operated by the FAA, in the U. S., faces challenges in managing the growing demand for U. S. air travel. U. S. air- traffic controllers often rely on outdated technologies that routinely overwhelm the system and compel aviation operators to fly inefficient, indirect routes resulting in delays and increased operational cost. For example, in January 2023, the FAA experienced an unexpected technical system outage that resulted in all domestic commercial air traffic being temporarily grounded for several hours, which adversely impacted airlines and private aviation industry operators during the duration of the outage. There have also been recent instances where understaffing of certain U. S. air traffic control systems have led to flight delays and cancellations, and resulted in significant costs to aviation operators. These instances are capable of repetition and may harm our business and results of operations in the future. In addition, discussions regarding privatization of the U. S. air traffic control system are ongoing, which could adversely affect our business. Further, implementation of the Next Generation Air Transport System by the FAA could result in changes to aircraft routings and flight paths that could lead to increased noise complaints and lawsuits, resulting in increased costs. Our aircraft operations are subject to significant governmental regulation and changes in government regulations imposing additional requirements and restrictions on our aircraft operations could increase our operating costs and result in service delays and disruptions. All interstate air carriers, including us, are subject to regulation by the DOT, the FAA and other governmental agencies. The laws enforced by these agencies impose substantial costs on us, may reduce air travel demand, and also may restrict the manner in which we conduct our business now or in the future, resulting in a material adverse effect on our operations. We also incur substantial costs in maintaining our current certifications and otherwise complying with the laws and regulations to which we are subject, including airworthiness directives. An adverse decision by a federal agency may have a material adverse effect on our operations, such as an FAA decision to ground, or require time consuming inspections of or maintenance on, all or any of our aircraft. Our business may also be affected if government agencies shut down for any reason or if there is significant automation or another operational disruption, such as those attributed to air traffic control or weather. In addition, we are subject to restrictions imposed by federal law on foreign ownership of U. S. airlines and aircraft including oversight by the DOT in maintaining our status as a U. S. Citizen (as such term is set forth in Title 49, U. S. Code, Section 40102 and administrative interpretations thereof issued by the DOT or its predecessor or successors, or as the same may be from time to time amended). A failure to comply with or changes to these restrictions may materially adversely affect our business. Revocation of permits, approvals, authorizations and licenses. Our aircraft operations require a variety of federal, state and local permits, approvals, authorizations and licenses. Our aircraft operations are subject to regulations and

requirements and may be adversely affected if we are unable to comply with existing regulations or requirements or if changes in applicable regulations or requirements occur. Our aircraft maintenance costs will increase as our fleet ages. Our aircraft maintenance costs will increase as our fleet ages. Currently, most of the parts on our aircraft are under multi- year warranties, but many of these warranties will expire in the coming years. If any maintenance provider with whom we have a flight hour agreement fails to perform or honor such agreements, we could incur higher interim maintenance costs until we negotiate new agreements. Any unexpected increase in maintenance costs may negatively impact our financial position and results of operations. Our inability to acquire additional aircraft may adversely affect operations. Additional aircraft may be needed to service our customers and grow our business. The inability to acquire sufficient aircraft in the secondary market at acceptable prices could adversely affect our business and could jeopardize our ability to meet the demands of our customers or result in continued reliance on third- party charter operations that could result in additional costs or lower reliability. Typically, aircraft manufacturers have a significant backlog of orders resulting in new orders being scheduled more than a year after execution of purchase agreements. Furthermore, manufacturers can face production delays due to many factors, including natural disasters, pandemics, supply chain disruptions, labor strikes or availability of skilled labor. Risks Related to Our Business Failure to maintain an ethical and inclusive corporate culture, or damage to our reputation, could have a material adverse effect on our business. We strive to create a culture in which our employees act with integrity, treat each other with respect and consider themselves empowered to report suspected misconduct. Our ability to attract and retain a high- quality workforce depends upon our commitment to a diverse and inclusive environment, along with our perceived trustworthiness and ethics. Issues can arise in any number of circumstances, including employment- related offenses such as workplace harassment and discrimination, regulatory noncompliance, failure to properly use and protect data and systems, and violations of our employee policies, as well as from actions taken by regulators or others in response to such conduct. Addressing allegations of misconduct detracts focus from business operations and is expensive. We have adopted policies to promote compliance with laws and regulations as well as to foster a respectful workplace for all employees. These policies, which include a code of business conduct and ethics, an insider trading policy, a Regulation FD policy, a sexual harassment policy, a regulated fraternization policy, and a whistleblower policy, are a component of our effort to minimize employee misconduct as well as activities that frequently result in allegations of misconduct **. We continuously assess our policies and provide training to our employees** , but our employees may fail to abide by these policies. In addition to damaging our reputation, actual or alleged misconduct could affect the confidence of our shareholders, regulators and other parties and could have a material adverse effect on our business, financial condition and operating results. Failure to protect our information technology infrastructure against cyber- based attacks, network security breaches or data corruption could materially disrupt our operations and adversely affect our business and operating results. The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, donor and patient data, customer service and technical support functions. ~~Our~~ **However, our** information technology systems are vulnerable to damage or interruption **, including** from earthquakes, fires, floods and other natural disasters; terrorist attacks; cyber- based attacks; attacks by computer viruses or hackers; **insider sabotage; ransomware;** power losses, computer system or data network failures; security breaches and data corruption. The failure of either our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages, all of which could materially and adversely affect our business, financial condition, operating results **, reputation, regulatory compliance, litigation exposure** , cash flows and prospects. In addition, our software systems include cloud- based applications that are hosted by third- party service providers with security and information technology systems subject to similar risks **, and we may not have accurate or complete information about the risks they face or the security of their systems** . As the cyber- threat landscape evolves, attacks are growing in frequency, sophistication and intensity, ~~and~~ are becoming increasingly difficult to detect **, and are being perpetrated by a broadening array of threat actors, including criminal hackers, hacktivists, nation- states and state- sponsored actors, perpetrators of industrial espionage and sabotage, and inside threats** . New and expanding threats to our information systems, including computer viruses, ransomware and phishing attacks **, insider attacks,** and more sophisticated and targeted cyber- related attacks, as well as cybersecurity failures resulting from human error and technological errors, pose a risk to the security of our systems and the systems of our customers, business partners and suppliers, as well the confidentiality, availability and integrity of the data we process. ~~In addition, there are numerous and evolving risks to cybersecurity, including criminal hackers, hacktivists, state- sponsored intrusions, industrial espionage, employee malfeasance and human or~~ **For example, during the second quarter of 2023, we became aware of an infiltration of portions of our information** ~~technological~~ **technology** ~~error~~ **network. As part of our investigation into this incident, we engaged outside security experts and identified unauthorized theft of data although no sensitive data were involved and we do not store patient related data on our network or anywhere within the company premises** . We ~~also~~ **have implemented additional security safeguards that we believe have secured the system, however, these additional security safeguards may not be successful. While the impact from this incident was not material to the operations of the Company, future impacts from such threats may be material. While we maintain insurance coverage for these types of incidents, such policies, may not provide coverage for, or offset the costs of responding to and remediating this infiltration or any other such incidents or any other liability that may arise from this infiltration or any other such incident. We** have access to sensitive, confidential or personal data or information that is subject to privacy and security laws, regulations or customer- imposed controls. Despite our implementation of controls **designed** to protect our systems and sensitive, confidential or personal data or information, we **have suffered the infiltration described above (and** may **have suffered other intrusions in the past) and may in the future** be vulnerable to material security breaches, theft, misplaced, lost or corrupted data, employee errors and / or malfeasance (including misappropriation by departing

employees) that could potentially lead to the compromising of sensitive, confidential or personal data or information. While we attempt to mitigate these risks by employing a number of measures, including employee training and maintenance of protective systems, such measures **did not prevent the infiltration described above and** may not prove adequate to prevent cyberattacks, and we remain potentially vulnerable to additional known or unknown threats. The impact from such threats could be material. A significant cybersecurity incident could result in a range of potentially material negative consequences for us, including lost revenue; unauthorized access to, disclosure, modification, misuse, loss or destruction of company systems or data; theft of sensitive, regulated or confidential data, such as personal identifying information or our intellectual property; the loss of functionality of critical systems through ransomware, denial of service or other attacks; business delays, service or system disruptions, damage to equipment and injury to persons or property, and increased insurance premiums. The costs and operational consequences of defending against, preparing for, responding to and remediating an incident may be substantial. Further, we could be exposed to litigation, regulatory enforcement or other legal action as a result of an incident, carrying the potential for damages, fines, sanctions or other penalties, as well injunctive relief requiring costly compliance measures. ~~A~~ **Any** cybersecurity incident could also impact our brand, harm our reputation and adversely impact our relationship with our customers, employees and stockholders. Economic, political and other risks associated with foreign operations could adversely affect our international sales and our results of operations. Because we market the OCS in countries in Europe, Asia- Pacific, Central Asia and Canada and plan to market it in other international markets, we are subject to risks associated with doing business internationally. During the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ **, 6 %** , 10 % ~~,~~ **and** 28 ~~% and 25~~ %, respectively, of our revenue was generated from customers located outside of the United States. We anticipate that international sales will continue to represent a ~~meaningful~~ portion of our total sales. In addition, some of our employees and suppliers are located outside of the United States. Accordingly, our results of operations could be harmed by a variety of factors, including: • changes in a country' s or region' s political or economic conditions; • longer payment cycles of foreign customers and difficulty of collecting receivables in foreign jurisdictions; • different or changing regulatory or insurance practices regarding reimbursement for transplant procedures; • difficulties in developing effective marketing campaigns in unfamiliar foreign countries; • trade protection measures, import or export licensing requirements or customs clearance and shipping delays; • fluctuations in foreign currency exchange rates; • differing tax laws and changes in those laws in the countries in which we are subject to tax, or potentially adverse tax consequences, including the complexities of foreign value- added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings; • changes in international legislation or regulations governing the approval or clearance process for the OCS or ongoing compliance requirements; • differing business practices associated with foreign operations; • difficulties in staffing and managing our international operations; • political, social, and economic instability abroad, terrorist attacks, and security concerns in general; • the burdens of complying with a wide variety of foreign laws and different legal standards, such as anti- bribery laws, including the FCPA, and UK Bribery Act of 2010, or the Bribery Act, data privacy requirements, labor laws and anti- competition regulations; • differing protection of intellectual property; and • increased financial accounting and reporting burdens and complexities. We rely on shipping providers to deliver products to our customers globally. Labor, tariff or World Trade Organization- related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock and offload our products, energy- related tie- ups or other factors could disrupt or delay shipping or off- loading of our products domestically and internationally. Such disruptions or delays could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. If one or more of these risks are realized, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected. Our success depends on our ability to retain our founder and President and Chief Executive Officer and other members of our management team and to attract, retain and motivate qualified personnel. Our success depends on our continued ability to attract, retain and motivate highly qualified clinicians, surgeons, scientists, engineers, managers and sales personnel. Dr. Waleed H. Hassanein, our founder and President and Chief Executive Officer, and other members of our management team are important to the success of our operations ~~and to our efforts to develop and commercialize the OCS~~ . All of these key employees, including Dr. Hassanein, are at- will employees and can terminate their employment with us at any time. The loss of any of these key members of our management team and, in particular, Dr. Hassanein, could impede our achievement of our research, development and commercialization objectives. We maintain **a** ~~$ 1. 0 million of~~ " key person " insurance policy on the life of Dr. Hassanein, but we do not maintain such insurance on any of our other employees. In addition, our expected growth will require us to hire a significant number of qualified personnel, including clinical development, regulatory, sales, marketing, engineering, scientific, clinical **, logistics and aviation** support and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we might not be able to sustain our operations or become profitable. The failure to manage our growth effectively could harm our business. To manage our anticipated future growth effectively, we must enhance our manufacturing and sterilization capabilities, information technology infrastructure and financial and accounting systems and controls. Our growth will require significant capital expenditures and may divert financial resources from other projects, such as the development of the OCS for transplants involving additional indications or other organs. Our **NOP** ~~National OCS Program~~ , an innovative turnkey solution to provide outsourced organ retrieval ~~and~~ **,** OCS organ management **and logistics services** , will also require additional capital expenditures. If we are unable to effectively manage our growth, our expenses may increase more than expected, our revenue could grow more slowly than expected and we might not be able to achieve our research and development and commercialization goals, which in turn could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. If we pursue acquisitions....., financial condition, results of operations and prospects. If we infringe or are alleged to infringe the intellectual property rights of third parties or are otherwise subject to

litigation or other proceedings regarding our intellectual property rights, our business or competitive position could be adversely affected. Our commercial success will depend in part on not infringing, misappropriating or otherwise violating the patents or other intellectual property or proprietary rights of others. Significant litigation regarding patent and other intellectual property rights occurs in the medical device industry. Third parties may claim that the OCS or aspects or uses of the OCS infringe intellectual property rights for which we do not hold licenses or other rights in the United States and abroad. Third parties in both the United States and abroad may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. For example, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non- practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management' s attention being diverted to patent litigation. If any third- party patents were asserted against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that the asserted third- party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize our products. In order to successfully challenge the validity of any U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. We may choose or, if we are found to infringe a third party' s patent rights and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing any of our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or products. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects. Our industry has experienced substantial litigation and other proceedings regarding patent and other intellectual property rights and lawsuits to protect or enforce our patents and other intellectual property rights could be expensive, time- consuming and unsuccessful. In addition to infringement claims against us, we may become a party to other types of patent litigation and other proceedings, including post- grant proceedings declared by the United States Patent and Trademark Office, or USPTO, and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to the OCS. For example, we may be subject to a third- party preissuance submission of prior art to the USPTO, or become involved in post- grant review procedures, oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete. Patent litigation and other proceedings may also absorb significant management time. In addition, competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming and divert the time and attention of our management. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. A court may disagree with our allegations and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third- party technology in question. Furthermore, the other party could counterclaim that we infringe their intellectual property or counterclaim that a patent we have asserted against them is invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property rights are non- infringed, invalid, or unenforceable. The outcome of any such proceeding is generally unpredictable. An adverse result in any litigation proceeding could put one or more

of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our products, we would lose at least part, and perhaps all, of the patent protection covering such product. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. Any of these outcomes would have a material adverse effect on our business. Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business. If we are unable to establish, maintain or adequately protect our intellectual property rights relating to the OCS, the commercial value of the OCS will be adversely affected and our competitive position could be harmed. Our success and ability to compete depend in part upon our ability to establish and maintain intellectual property rights covering the OCS in the United States and other countries. We own ~~or have an exclusive license under~~ several patents and patent applications in the United States and corresponding patents and patent applications in a number of foreign jurisdictions. With respect to the patents and patent applications that we own, any patents that have or may issue from our currently issued or pending patent applications would be expected to expire between 2025 and ~~2036~~ **2043**, assuming all required fees are paid. However, we cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our OCS technology, any additional features we develop for our OCS technology or any new products. Other parties may have developed technologies that may be related to or competitive with our system, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Even if issued, our patents may be challenged, narrowed, held unenforceable, invalidated or circumvented, or others could challenge the inventorship, ownership or enforceability of our patents and patent applications, any of which could limit our ability to stop competitors from marketing similar products or limit the term of patent protection we may have for our products, or cause us to lose our right to manufacture, market and sell the OCS products or components of the OCS products. Additionally, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. In addition, the Leahy- Smith Act has transformed the U. S. patent system into a first- to- file system. The first- to- file provisions became effective on March 16, 2013. It is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. For example, the Leahy- Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, which in turn could diminish the commercial value of the OCS. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. 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 the OCS; • 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 any 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. If we are unable to obtain patent term extension under the Hatch- Waxman Act, our business may be materially harmed. Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U. S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Act. The Hatch- Waxman Act permits a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope

of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenue could be materially adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be materially adversely affected. We may be unable to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. If we are unable to protect the confidentiality of our trade secrets, the value of the OCS and our business and competitive position could be harmed. In addition to patent protection, we also rely upon trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. We also have agreements with our employees, consultants and third parties that obligate them to assign inventions made in the course of their work for us to us, however these agreements may not be self-executing, not all employees or consultants may enter into such agreements, or employees or consultants may breach or violate the terms of these agreements, and we may not have adequate remedies for any such breach or violation. If any of our intellectual property or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, the value of the OCS and our business and competitive position could be harmed. 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, hospitals or other third parties. 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, competitors or other third parties. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against 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 or a settlement payment, a court could prohibit us from using technologies, features or other intellectual property 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, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position, 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 representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. Risks Related to Government Regulation Even after approval for the OCS, we are subject to continuing regulation by regulatory authorities and entities in the United States and other countries, and if we fail to comply with any of these regulations, our business could suffer. Even after approval of the OCS for a specific indication, we are subject to extensive continuing regulation by the FDA and other regulatory authorities and entities. We are subject to Medical Device Reporting regulations, which require us to report to the FDA if we become aware of information that reasonably suggests our product may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device we market would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to 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 maintain records of other corrections or removals. The FDA closely regulates promotion and advertising and all claims that we make for the OCS. If the FDA determines that our promotional materials, training or advertising activities constitute promotion of an unapproved use of the OCS, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement actions by the FDA or state agencies, which may include any of the following sanctions: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • recall, suspension or termination of distribution, administrative detention, injunction or seizure of organ- specific OCS Consoles or disposable sets; • customer notifications or repair, replacement or refunds; • refusing or delaying our requests for premarket approval of new products or for modifications to existing products, and refusing or delaying our requests for PMAs for new intended uses of the OCS; • withdrawing or suspending PMA approvals that have already been granted, resulting in prohibitions on sales of our products; • FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and Any corrective action, whether voluntary or involuntary, as well as potentially 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. For our currently marketed OCS Lung, OCS Heart and OCS Liver, as part of the conditions of approval, we must complete PMA post- approval studies. For example, ~~three~~ -- **the** ~~post- approval studies must be completed for OCS Lung including, the OCS Lung INSPIRE Continuation PAS, which is a two- arm observational study intended to evaluate long- term outcomes of the OCS Lung INSPIRE Trial patients, the OCS Lung EXPAND Continuation PAS, which is a single arm study intended to evaluate long- term outcomes of the OCS Lung EXPAND Trial patients, and our~~ OCS Lung TOP Registry **must be completed** , which is a prospective, single- arm, multi- center, observational study designed to evaluate short- and long- term safety and effectiveness of the OCS Lung for both donor lungs currently utilized and unutilized for transplantation. Our TOP Registry entails submission of regular reports to the FDA. Failure to comply with the conditions of approval can result in material adverse action, including withdrawal of the approval. We also are required to comply with strict post- marketing obligations that accompany the affixing of the CE Mark to medical devices in the European Union. These include the obligation to report incidents which meet the criteria for reporting, and to provide periodic safety update reports and trend reports. Additionally, national competent authorities in the European Union also closely monitor the marketing programs implemented by device companies. The obligations that companies must fulfill concerning premarketing approval of promotional material vary among member states of the European Union. A failure to comply with our obligations in marketing and promoting the OCS in the European Union could harm our business and results of operations. In addition, certain changes and other events with respect to regulatory approvals may cause an event of default under our CIBC Credit Agreement. See " Item 7. Management' s Discussion and Analysis- Long- Term Debt, " in this Annual Report on Form 10- K. Our products have been and may in the future be subject to product recalls that could harm our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. The OCS must be manufactured in accordance with federal and state regulations, and we or any of our suppliers or third- party manufacturers could be forced to recall our installed systems or suspend or terminate production if we fail to comply with these regulations. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the recall order must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us could occur as a result of component failures, security failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that recalls initiated to 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 be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, we could be required to report those actions as recalls. A recall announcement could harm our reputation with customers and negatively affect our sales. Additionally, 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. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted, including warning letters, untitled letters, administrative actions, criminal

prosecution, imposition of civil monetary penalties, ~~revocation of our device approval (s),~~ seizure of our products or delay in clearance or approval of future products. We have voluntarily recalled certain OCS products from clinical sites in the past and may need to take similar actions in the future, which may result in notices to regulatory agencies in other jurisdictions. As we continue to expand commercialization of our products and sell OCS products to new customers, the impact of any future product recall increases, and any future product recalls would require greater administrative and response efforts than historical product recalls. Internationally, the approaches to product defects will vary. A product may be recalled in one country but not in others. However, within the European Union, competent authorities are required without delay to take corrective action against a device (including withdrawal / recall of a device) and notify other national competent authorities, the European Commission and notified bodies (as applicable) of any devices that present an unacceptable risk to the health or safety of patients, users or other persons, or other aspects of the protection of public health. Other non- compliance with the MDR may also lead to corrective action being taken and notifications being sent if the non- compliance is not rectified within a given time period (as determined by the competent authority). Therefore, a recall in one EU member state may lead to recalls in the rest of the European Union. If we fail to maintain necessary FDA approvals for the OCS, or obtain necessary FDA approval for future uses of the OCS, we will not be able to commercially sell and market the OCS. The OCS products are medical devices subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. The FDA regulates the design, development, testing, manufacturing, labeling, selling, promoting, distributing, importing, exporting and shipping of the OCS. We have obtained a PMA for each of the OCS Lung, OCS Liver and OCS Heart for both DBD and DCD indications. We received 510 (k) clearances for the OCS Lung Solution for cold flush, storage and transportation of donor lungs in July 2021, ~~and~~ for the OCS Lung Donor Flush Set in November 2022 **, and for the OCS Heart Leukocyte Reducing Filter in October 2023** . PMA approval could be withdrawn or other restrictions imposed if post- market data demonstrate safety issues or inadequate performance. The FDA can also require removal of 510 (k) cleared devices from the market in case of safety issues. If we are not able to maintain the necessary regulatory approvals for the OCS, or obtain the necessary regulatory approvals or clearances for future products on a timely basis or at all, our financial condition and results of operations would suffer, possibly materially, and our business might fail. If we fail to maintain the CE Mark in the European Union, Northern Ireland and the UKCA mark (as applicable) in Great Britain, we will not be able to commercially sell and market the OCS in the EU **or UK** . In the European Union, we have the right to affix a CE Mark for the sale of the OCS Lung, OCS Heart and OCS Liver for lung, heart and liver transplants, respectively. Our notified body, BSI, is based in the Netherlands and issues the certificates that allow CE marking of the OCS products. Our sales in the EU are dependent on obtaining and maintaining the CE Mark certifications for each of our OCS products. As required by the MDR, we received recertification of the CE Mark in September 2022 for each of the OCS Heart **and OCS Lung systems** , **which includes the OCS Console, the OCS disposables, and the OCS solution additives. We also received the recertification of the CE Mark in September 2022 for the** OCS Liver Console ~~(~~and disposables ~~) and OCS Lung systems, which includes the OCS Console, the OCS disposables, and the OCS solution additives~~ . We ~~have applied for and expect to receive~~ **received** the CE Mark for the OCS Liver combined with our solution additives under the MDR **in May 2023,** ~~within~~ -- **with** ~~the next 12 months~~ **an effective date of April 2023** . In order to be able to continue to use the CE Mark we will have to meet the conditions set out in the MDR. Post- Brexit the MDR applies in Northern Ireland in accordance with the Northern Ireland Protocol but does not apply in Great Britain (England, Wales and Scotland). The UK Medical Devices Regulations 2002 (UK MDR 2002) provided a transitional period under which the UK will recognize EU CE marks **and the** ~~until June 30, 2023. The~~ MHRA has confirmed that this will be extended **potentially** until June 30, ~~2024~~ **2030 (subject to certain conditions)** . To be placed on the market in Great Britain after this date, medical devices must have undergone a conformity assessment in accordance with the UK MDR 2002 and have the UKCA mark affixed. However, even devices that benefit from the transition period must still comply with the other requirements of the UK MDR 2002; for example, there are broader registration requirements with the Medicines and Healthcare products Regulatory Agency, or the MHRA, and if the manufacturer is located outside the UK, a UK Responsible Person must be appointed. To continue to place products on the market in the European Union and United Kingdom, we will need to meet the conditions set out in the EU MDR or UK MDR ~~2022~~ - **2002** , as applicable. We might not be able to continue to place the devices on the market in the European Union and / or United Kingdom for any current use of the OCS if we are not able to maintain certifications of our products for their current use under the MDR and / or obtain certification under the UK ~~MD0R~~ - **MDR** 2002 when required. If any variation in the uses for which the CE / UKCA ~~Mark~~ **mark** has been affixed to the OCS requires us to perform further research or to modify the technical documentation required to affix the CE / UKCA mark, our revenue and operating results could be adversely affected and our reputation could be harmed. If we fail to obtain and maintain regulatory approval in foreign jurisdictions, our market opportunities will be limited. FDA clearance or approval or a CE mark does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary market authorizations to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration. For example, if, as a result of manufacturing error, the efficacy of our products does not meet the standards claimed in the accompanying instructions for use, regulatory authorities could prevent our products from being placed on the market in the European Union, Northern Ireland, Great Britain and elsewhere. If transplant centers and hospitals cannot obtain adequate reimbursement or funding from governments or third- party payors for purchases of the OCS and additional disposable sets and for costs associated with procedures that use the OCS and the **NOP** ~~National OCS Program~~ , our prospects for generating revenue and achieving profitability will suffer materially. Our prospects for generating revenue and achieving profitability depend heavily upon the availability of adequate reimbursement or funding in both the United States and other markets for purchases of the OCS and for organ transplant procedures that use the OCS and the **NOP** ~~National OCS Program~~ . In the United

States, Medicare generally reimburses the facilities in which transplant procedures are performed based upon prospectively determined amounts. For hospital inpatient treatment, the Medicare prospective payment generally is determined by the patient' s condition and other patient data and procedures performed during the patient' s hospital stay, using a classification system known as MS- DRGs. Prospective rates are adjusted for, among other things, regional differences and whether the hospital is a teaching hospital. Because prospective payments are based on predetermined rates and may be less than a hospital' s actual costs in furnishing care, hospitals have incentives to lower their inpatient operating costs by utilizing products, devices and supplies that will reduce the length of patients' hospital stays, decrease labor or otherwise lower their costs. In addition to these MS- DRG- based payments, Medicare reimburses transplant centers for " reasonable and necessary " organ acquisition costs, which are considered " pass- through " costs from the prospective payment system, and are not based on the payments for the applicable MS- DRG. Pass- through organ acquisition costs include services required for the acquisition of an organ, such as tissue typing, organ preservation, transport of organs, donor evaluation and other acquisition costs. The separate payments for these costs are determined on a reasonable cost basis established through the transplant center' s Medicare cost report. The costs incurred by transplant centers for the organ- specific OCS Console, OCS Perfusion Sets and OCS Solutions are classified as organ acquisition costs for which Medicare provides additional reimbursement. However, Medicare does not reimburse for items determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury. The CMS and Medicare contractors who administer Medicare around the country have substantial discretion in determining whether the OCS is reasonable and necessary in this context. Either CMS or a Medicare contractor might determine that Medicare will not cover and reimburse for the cost of the OCS in the absence of reliable clinical data evidencing the benefits to patients of the use of the OCS. The data we collect from our prior, ongoing and planned clinical studies and patient registry may not be sufficient for this purpose in a coverage determination by CMS or a Medicare contractor. Accordingly, Medicare might not reimburse transplant centers for all or a portion of the cost of the OCS. We believe that private insurers and other public insurers in the United States generally will follow the coverage and payment policies of Medicare. Outside of the United States, reimbursement and funding systems vary significantly by country, and within some countries, by region. Many foreign markets have government managed healthcare systems that govern reimbursement and funding for medical devices and procedures. In the European Union member states, the costs associated with organ transplant procedures may be paid for by national insurance and in some cases private insurers or by both national insurance and private insurers, depending on the priorities established by individual programs. These reimbursement arrangements are subject to complex rules and regulations at the national and regional levels that can vary between member states of the European Union and may require that we perform additional clinical studies to demonstrate that the OCS is superior to existing preservation methods. We have no studies currently planned to collect such clinical data, and any studies of this kind likely would be expensive and lengthy and may not ultimately produce results adequate to secure reimbursement. In some cases, we might not be able to secure adequate reimbursement for the OCS at all or until we have collected additional clinical data supporting the benefits associated with the use of the OCS in transplant procedures. Hospitals or surgeons in countries or regions where separate additional reimbursement or funding for the OCS is not available may determine that the benefits of the OCS do not or will not outweigh the cost of the OCS. Alternatively, we may be required to enter into risk sharing arrangements with payers. Adoption of our products in the European Union may be hindered if they impede our customer' s compliance with the requirements of Directive 2010 / 53 / EU (formerly Directive 2010 / 45 / EU), and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Statutory Instrument (SI) 2012 No. 1501) (the Regulations) in the United Kingdom which imposes certain standards on procurement, preservation and transport of organs intended for transplantation. Even where reimbursement or funding is available, in some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, reimbursement and pricing negotiations with governmental authorities can take considerable time after the CE marking of a product. For example, some foreign reimbursement systems provide for limited payments in a given period and, therefore, result in extended payment periods, which could hinder adoption of the OCS for use in transplantation, limiting sales. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products in certain foreign countries, which could negatively affect the long- term growth of our business. Even if existing reimbursement and funding arrangements of governmental programs and other third- party payors provide for sufficient payments to make purchases of the OCS cost- effective for hospitals, the laws and regulations governing these arrangements are subject to change. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs could lead to legislative or regulatory reform of the United States or foreign reimbursement and funding systems in a manner that significantly reduces or eliminates reimbursement for the OCS or for transplant procedures. If hospitals in the United States or the European Union are not able to obtain reimbursement or funding for the cost of the OCS and additional disposable sets or for transplant procedures generally, they may not have sufficient economic incentives to purchase the OCS. If hospitals or surgeons determine that the benefits of the OCS do not or will not outweigh the initial cost and ongoing expense of the OCS, we might fail to achieve significant sales and may never become profitable. Reimbursement in international markets is likely to require us to undertake country- specific reimbursement activities, including additional clinical studies, which could be time- consuming and expensive and may not yield acceptable reimbursement rates. In international markets, market acceptance of our products will likely depend in large part on the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and by region in some countries, and include both government- sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. In addition, even if we do obtain international reimbursement approvals, the level of reimbursement may not be enough to commercially justify expansion of our business into the approving jurisdiction. To the extent we or our customers are unable to obtain reimbursement for products in major international markets in which we seek to market and sell our products, our international revenue growth would be harmed, and our business and results of

operations would be adversely affected. If we modify our products, we may be required to obtain approval of new PMAs or PMA supplements, vary existing CE Marking, and may be required to cease marketing or recall any modified products until the required approvals are obtained. Certain modifications to a PMA- approved device **or to its manufacturing processes** require approval of a new PMA or a PMA supplement, while other modifications can be reported in an annual report or through a 30- day Notice. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our approved devices and manufacturing processes in the future that we believe do not require approval of a new PMA application or PMA supplement, or submission of a 30- day Notice. If the FDA disagrees with our determination and requires us to submit a new PMA, PMA supplement or 30- day Notice for modifications to our previously approved products or manufacturing processes, we may be required to cease marketing or to recall the modified product until we obtain approval or submit the 30- day Notice, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve our products for any future indications that are desirable for commercialization or could require clinical trials to support any modification to the device or any modified indications or claims. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Additionally, any significant change to the quality system or the product range in relation to a CE Marked device will require notification to the notified body which certified the product. The notified body will assess the proposed change. We might not be able to have the CE Mark varied without taking additional steps, or at all. For example, we might need to conduct additional clinical trials and provide additional technical information to the appropriate notified body before the CE Mark can be affixed to the changed product. If we fail to comply with the FDA' s QSR, or FDA or EU requirements that pertain to clinical trials or investigations, the FDA or the relevant EU competent authority could take various enforcement actions, including halting our manufacturing operations, and our business would suffer. In the United States, as a manufacturer of a medical device, we are required to demonstrate and maintain compliance with the FDA' s QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical devices **. In February 2024 FDA issued the QSMR Final Rule to amend the QSR, incorporating by reference ISO 13485: 2016. Until the QSMR becomes effective on February 2, 2026, we are required to comply with the QSR** . The FDA enforces the QSR through periodic inspections and unannounced " for cause " inspections. We are subject to periodic FDA inspections to determine compliance with QSR and pursuant to the Bioresearch Monitoring Program, which have in the past and may in the future result in the FDA issuing Form 483s, including during the conduct of clinical trials. Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the International Organization for Standardization. For example, in the European Union the MDR includes detailed requirements for clinical investigations, which are in line with the international standard ISO 14155: 2020 on good clinical practical, or GCP. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. Our failure to comply with FDA or local requirements that pertain to clinical trials / investigations, including GCP requirements, and the QSR (in the United States), or failure to take satisfactory and prompt corrective action in response to an adverse inspection, could result in enforcement actions, including a warning letter, adverse publicity, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing our products, refusal to permit the import or export of our product, prohibition on sales of our product, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to suffer. We may not be able to obtain or maintain regulatory qualifications outside the United States, which could harm our business. Sales of the OCS outside the United States are subject to foreign regulatory requirements that vary widely from country to country. The foreign regulatory approval process generally includes all of the risks associated with obtaining FDA clearance or approval in addition to other risks. Complying with international regulatory requirements can be an expensive and time-consuming process, and approval is not certain. The time required to obtain foreign clearances or approvals may exceed the time required for FDA clearance or approval, and requirements for such clearances or approvals may differ significantly from FDA requirements. Foreign regulatory authorities may not clear or approve our product for the same uses cleared or approved by the FDA. In addition, we may not be able to affix the CE Mark to new or modified products and we may fail to obtain any additional regulatory qualifications, clearances or approvals or to comply with additional legal obligations required by the individual member states of the European Union or other countries in which we seek to market the OCS. The FDA also regulates the export of medical devices from the United States. If we are not successful in obtaining and maintaining foreign regulatory approvals or complying with U. S. export regulations, our business will be harmed. Foreign regulatory agencies periodically inspect manufacturing facilities both in the United States and abroad. While we implement corrective and preventive action related to any inspection observations, we may fail to pass future inspections of our facility by applicable regulatory authorities or entities both in the United States and in other countries. Delays in receiving necessary qualifications, clearances or approvals to market our product outside the United States, or the failure to receive those qualifications, clearances or approvals, or to comply with other foreign regulatory requirements, could limit or prevent us from marketing our products or enhancements in international markets. Additionally, the imposition of new requirements could significantly affect our business and our product, and we might not be able to adjust to such new requirements. If we fail to comply with applicable foreign regulations, we could face substantial penalties and our business, financial condition, operating results, cash flows and prospects could be adversely affected. We could face product liability suits or regulatory delays due to defects in the OCS, which could be expensive and time- consuming and result in substantial damages payable by us and increases in our insurance rates. If our products are deemed to be defectively designed, manufactured or labeled, contain defective components, suffer security failures or are hacked, or are counterfeited, we could face substantial and costly litigation by transplant centers that purchase or use the OCS or by their patients or others claiming damages on their behalf. Moreover, transplantations are complex and inherently

risky medical procedures. Many of the patients currently on a waiting list for a lung, heart or liver transplant already are very sick, with some of them receiving intensive care. All of these patients have a significant risk of death if they do not receive a transplant. Thus, we may incur substantial liability if the OCS fails to perform as expected and, as a result of this failure, patients do not receive the intended transplants or receive transplants that are not successful. Although death is an anticipated adverse event of the organ transplant population, if the rate of deaths or other serious adverse events using the OCS is greater than expected using conventional transplant procedures, transplant surgeons may cease using the OCS as often or at all, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. Because the OCS represents a novel approach to organ transplantation, a patient or transplant center may choose to name us as a party to a lawsuit relating to the use of the OCS in connection with a planned or completed transplant procedure regardless of whether the OCS caused or contributed to a serious adverse event or death of a patient. Any claim, whether or not we are ultimately successful, could divert management' s attention from our core business, be expensive to defend and result in sizable damage awards against us. Currently, we maintain global product liability insurance covering damages of up to $ 10 million per occurrence for both the human clinical and commercial use of our product. We also maintain local insurance policies as required. Our current insurance coverage might not be sufficient to cover future claims and is subject to deductibles. Moreover, in the future, we may not be able to obtain insurance in amount or scope sufficient to provide us with adequate coverage against potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry, impair our current or future preclinical studies or clinical trials, hinder acceptance of our products in the market and reduce product sales. Furthermore, we would need to pay any product liability losses in excess of our insurance coverage or within the deductibles provided under our insurance policies applicable to the claim out of cash reserves, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. The FDA has warned that the threat of cyberattacks on medical devices is no longer theoretical. Hackers and other third parties may try to circumvent security controls on an OCS to gain access to information on the OCS, alter the way an OCS operates, to act as a trojan horse or other entry point to other systems that could lead to those systems suffering cybersecurity breaches or attacks, or to cause harms to transplanted organs or individuals. If our security controls fail to fully protect the OCS and the information on it, we could suffer reputational harm, could undergo regulatory investigations and enforcement, or could have claims brought against us. Third parties may attempt to produce counterfeit versions of our products, which may harm our ability to sell the OCS and its components, negatively affect our reputation or harm patients and subject us to product liability. Counterfeit medical devices are an increasing presence on the market. Third parties may seek to develop, manufacture, distribute and sell systems that we believe infringe our proprietary rights, which would compete against the OCS and impair our ability to sell the OCS in jurisdictions in which our proprietary rights are not upheld. In addition, counterfeit products may be promoted in a way that misleads consumers into believing they are affiliated with us. If a counterfeit version of the OCS were to appear on the market, we would expect to be obliged to verify all OCS products currently on the market, and possibly to withdraw all OCS products from the market while verifications are made. We also might be named in a lawsuit relating to any side effects or fatalities allegedly related to the use of a counterfeit OCS irrespective of whether the counterfeit device in fact contributed to such an adverse event or whether we were aware of the existence of the counterfeit device. Improper marketing or promotion of our products or misuse or off- label use of the OCS may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Our OCS products have been approved for marketing in the United States, European Union and other jurisdictions for specific indications, and our promotional materials and training methods must comply with regulatory requirements in the countries where they are sold. We train our commercial team to not promote the OCS for uses outside of the approved indications for use / intended purpose, known as " off- label uses. " We cannot, however, prevent a surgeon from using the OCS off- label, when in the surgeon' s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if surgeons attempt to use the OCS off- label. Furthermore, the use of the OCS for indications other than those approved by the FDA / by any foreign regulatory body or for which they are CE marked may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons and patients. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off- label use, or that the materials or training are false or misleading, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of **a warning letter,** an untitled letter ~~,~~ **(** which is used for violations that do not necessitate a warning letter **)** , injunction, seizure, civil fine or criminal penalties. In the EU the MDR expressly prohibits misleading claims in the form of off- label promotion and the MDR grants enforcement powers to national competent authorities. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws or consumer protection laws, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. In addition, surgeons may misuse the OCS or use improper techniques if they are not adequately trained, potentially leading to unsatisfactory patient outcomes, patient injuries, negative publicity and an increased risk of product liability. If the OCS is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Similarly, in an effort to decrease costs, surgeons may also reuse the component and accessories of the OCS that are intended for a single use or may purchase reprocessed OCS components from third- party reprocessors in lieu of purchasing new components from us, which could result in product failure and liability. As described above, product liability claims could divert management' s attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. Legislative or

regulatory reforms in the United States or other jurisdictions may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. From time to time, legislation is drafted and introduced in the U. S. Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. In the EU, Regulation (EU) 2017 / 745, or the MDR, repealed and replaced the Medical Devices Directive (93 / 42 / EEC) with effect from May, 26 2021. Although the MDR now applies so all new devices placed on the market must be CE marked under it, under the transition period granted by the MDR, certificates issued by notified bodies for medical devices under the Medical Devices Directive before May 26, 2021 **potentially** remain valid **(subject to certain Conditions) and the devices may continue to be placed on the EU market potentially** until the ~~period indicated~~ **end of December 2027 or 2028 (depending** on the ~~certificate~~ **class of device) and provided the manufacturer satisfies certain requirements** , ~~subject to all certificates becoming void on May 27, 2024~~ **including that there are no significant changes in the design and intended purpose of these devices** . Post- Brexit the MDR applies in Northern Ireland in accordance with the Northern Ireland Protocol but does not apply in Great Britain (England, Wales and Scotland). The UK Medicines and Healthcare products Regulatory Agency (MHRA) has provided a transitional period under which the UK will recognize EU CE marks until June 30, ~~2024~~ **2030 (subject to certain conditions)** . To be placed on the market in Great Britain after this date, medical devices must have undergone a conformity assessment in accordance with UK legislation and have the UKCA mark affixed. All of our products that were previously certified under the Medical Devices Directive, including OCS Heart, OCS Liver ~~Console (and disposables)~~ and OCS Lung systems, which includes the OCS Console, the OCS disposables, and the OCS solution additives, have now been recertified under the MDR. We ~~have also applied for and expect to receive~~ **received** the CE Mark for the OCS Liver combined with our solution additives under the MDR **in May 2023,** ~~within~~ -- **with** ~~the next 12 months~~ **an effective date of April 2023** . We also recognize that our products ~~will~~ **may** need to be certified and have a UKCA mark affixed to be placed on the market in Great Britain **in the future** ~~from July 1, 2024~~ . However, ~~following~~ **although neither** the ~~MHRA' s response to a consultation on~~ **EU MDR nor EU IVDR apply in Great Britain,** the **national UK** ~~future regulation of~~ medical devices ~~in~~ **rules currently allow manufacturers to place devices CE marked under the EU MDR or EU IVDR (including** ~~the~~ **their** ~~UK~~ **relevant transition periods) on** the **market in Great Britain, potentially up until June 30, 2030, provided certain conditions are met. The** UK Government is expected to publish updated UK medical devices legislation in ~~2023~~ **2025** . This might lead to substantial changes in the regulatory framework / requirements imposed on medical devices. **We will need** ~~This could slow our ability~~ to ~~obtain~~ **continue to monitor the developments in the UK to assess how** ~~the~~ **they impact** ~~necessary certification and we may have to take~~ our **devices sold** ~~product off the market~~ in Great Britain ~~until we obtain a UKCA mark.~~ We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly. There are numerous U. S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti- kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third- party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U. S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in substantial civil monetary and criminal penalties. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid; • the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill private payors. Private individuals can bring False Claims Act " qui tam " actions, on behalf of the government and such individuals, commonly known as " whistleblowers, " may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose substantial civil fines and penalties, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs; • the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary' s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; • HIPAA, which created additional federal criminal statutes that prohibit,

among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians and teaching hospitals. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in substantial civil monetary penalties; • many countries in which we operate have laws with extra- territorial effect- those laws apply to our operations outside the relevant country, to the extent they are breached. Examples of such laws include: the FCPA, Bribery Act and the GDPR. The extra- territorial effect of those laws affects our sales and marketing strategy, since in many countries healthcare professionals are officers of the state. This is particularly important in the context of bribery offences, which in the UK and in the United States include the offence of bribing a foreign public official. Failure by our sales staff to comply with those laws may result in criminal and civil penalties and damage our reputation; and • analogous state and foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any private payor, including commercial insurers or patients; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers. These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with customers, physicians or other potential purchasers of our products. In particular, these laws will influence, among other things, how we structure our sales offerings, including discount and rebate practices, customer support, education and training programs, and physician consulting and other service arrangements. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. For example, the member states of the European Union closely monitor perceived unlawful marketing activity by companies, including inducement to prescribe and the encouragement of off- label use of devices. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations. Moreover, industry associations closely monitor the activities of their member companies. If these organizations or national authorities were to name us as having breached our obligations under their laws, regulations, rules or standards, our reputation would suffer and our business, financial condition, operating results, cash flows and prospects could be adversely affected. Failure to comply with anti- bribery, anti- corruption, and anti- money laundering laws, including the FCPA, as well as export control laws, customs laws, sanctions laws and other laws governing our operations could result in civil or criminal penalties, other remedial measures and legal expenses. As we grow our international presence, we are increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U. S. Departments of Justice, Commerce, State and U. S. Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the FCPA and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the Bribery Act prohibits both domestic and international bribery, as well as bribery across both private and public sectors. The substantive offences of offering or receiving a bribe will be committed by an individual where either the bribery takes place in the U. K, or the person paying or receiving the bribe has a close connection with the UK An organization which is either incorporated in or carries on part of its business in the U. K will be liable under the Bribery Act if a person associated with the organization (being persons performing services for it) pays a bribe anywhere in the world intending to obtain or retain business for the organization. This is a strict liability offense with the only defenses available being that the organization implemented " adequate procedures " to prevent bribery or it was reasonable for it to not have such procedures in place. Under these laws and regulations, as well as other anti- corruption laws, anti- money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and

modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. Due to sales of our products to government or government- affiliated entities, we may be exposed to heightened risk of potential violations of the FCPA, the Bribery Act, or other relevant law. We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti- corruption, anti- money- laundering and anti- terrorism laws and regulations. We cannot ~~assure you~~ **be certain** , however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we **provide** ~~assure~~ **assurance** ~~you~~ that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti- corruption, anti- money laundering and anti- terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations. We are subject to, and may in the future become subject to additional, U. S., state and foreign laws and regulations imposing obligations on how we collect, store, process or share information concerning individuals. Our actual or perceived failure to comply with such obligations could harm our business. Complying with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue. In the conduct of our business, we may at times collect, process or share data concerning individuals, including health- related personal data. The U. S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U. S. federal rules, regulations and guidance concerning cybersecurity for medical devices, including guidance from the FDA. State privacy and cybersecurity laws vary and, in some cases, can impose more restrictive requirements than U. S. federal law. For example, the CCPA affords California residents expanded privacy rights and protections, including civil penalties for violations and statutory damages under a private right of action for data security breaches. These protections **were** ~~will be~~ expanded by CPRA **and more than a dozen states now** ~~, which will be operational in most key respects on January 1, 2023. Similar legislative proposals~~ have **similar laws** ~~passed or are being advanced in other states~~ . Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information. Our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies, procedures and systems. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions and penalties under such laws. Even if we are not determined to have violated applicable data laws, government investigations into these issues can be expensive and lengthy and generate adverse publicity, which could harm our business, financial condition, results of operations or prospects. The EEA and the UK, as well as other international jurisdictions, also have laws and regulations dealing with the collection, use and processing of personal data concerning individuals who are located there. Those laws are often more restrictive than those in the United States. For example, we are subject to the requirements of the GDPR, which imposes more stringent administrative requirements for controllers and processors of personal data, including, for example, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i. e., key- coded) data, additional obligations when we contract with service providers, and more robust rights for individuals over their personal data. The GDPR provides that EU member states may make their own further laws and regulations, including laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or cause our costs to increase, and harm our business and financial condition. If we do not comply with our obligations under the GDPR, we could be exposed to enforcement activity from EU regulators, including substantial fines and litigation. In addition, EU law restricts transfers of personal data to the United States unless certain requirements are met. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. For example, in July 2020, the Court of Justice of the European Union invalidated the U. S.- EU Privacy Shield Framework, which has led to increased scrutiny of data transfers from the EEA and the UK to the United States generally and may increase our costs of compliance with data privacy legislation. We rely on a mixture of mechanisms to transfer personal data from our European business to the United States. We are also subject to the laws of each EU member state implementing any EU directive applicable to our processing activities, including Directing 2002 / 58 / EC. We are subject to the requirements of the UK Data Protection Law as amended and superseded from time to time. UK Data Protection Law means: (i) the GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018; (ii) the Data Protection Act 2018; (iii) the Privacy and Electronic Communications (EC Directive) Regulations 2003 as they continue to have effect by virtue of section 2 of the European Union (Withdrawal) Act 2018; and (iv) any other laws in the field of data protection in force in the UK from time to time applicable (in whole or in part) to us. Any actual or perceived failure by us or the third parties with whom we work to comply with data privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of information concerning individuals, may result in governmental enforcement actions and investigations, including by European data protection authorities and U. S. federal and state regulatory authorities, fines and penalties, litigation and / or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations. Healthcare policy changes, including recently enacted or potential future legislation reforming the U. S. healthcare system, could harm our business, financial condition and results of operations. We operate in a highly regulated industry. The U. S. and state governments continue to propose and pass legislation or take administrative action

that may affect the availability and cost of healthcare. Healthcare reform initiatives could harm our business, financial condition and results of operations. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs **and improve access to transplantation** . There have been and will likely continue to be ongoing healthcare reform efforts. These reform efforts have and may continue to focus on coverage and payment for organ procurement and transplant. For example, the Centers for Medicare & Medicaid Services issued regulations in 2020 and 2021 that revised Medicare conditions of participation for organ procurement organizations as well as organ acquisition payment policies for organ procurement organizations, transplant centers and donor hospitals **. In addition, in 2023, the Securing the U. S. Organ Procurement and Transplantation Network act was signed into law, which allows HRSA to make changes to the Organ Procurement and Transplantation Network (OPTN), including requiring an independent board, awarding contracts to both non- profit and for- profit entities, and eliminating the cap on funding** . We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit coverage or reimbursement for healthcare products and services or otherwise result in reduced demand for the OCS or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, coverage or reimbursement of services provided by organ procurement organizations, transplant centers or hospitals could affect demand for the OCS, which in turn could have a material adverse effect on our business, financial condition and results of operations. In addition, other broader legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' commercial success. The Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2030 (except May 1, 2020 to March 31, 2022). Any significant spending reductions affecting Medicare, Medicaid, or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenue. Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences. Our research and development programs involve the controlled use of hazardous materials. Accordingly, we are subject to international, federal, state and local laws governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with applicable regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or failure to comply with environmental laws, we could be held liable for damages that result, and any such liability could exceed our assets and resources. Our general liability and umbrella insurance policies provide for coverage up to annual aggregate limits of $ 2 million per occurrence but exclude coverage for liabilities relating to the release of pollutants. The insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury due to pollution conditions or other extraordinary or unanticipated events. Furthermore, an accident could damage or force us to shut down our operations. Risks Related to Our Common Stock and General Risks The market price of our common stock has been and may continue to be volatile and could subject us to securities class action litigation. During the year ended December 31, ~~2022~~ **2023** , the price per share of our common stock has ranged from as low as $ ~~10~~ **36** . ~~00~~ **42** to as high as $ ~~64~~ **99** . ~~36~~ **63** . Some of the factors that may cause the market price of our common stock to fluctuate include: • price and volume fluctuations in the overall stock market; • volatility in the market price and trading volume of comparable companies; • actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts; • results of post-approval studies or clinical trials relating to next generation products for the OCS or competing products; • failure or discontinuation of any of our product development and research programs; • regulatory or legal developments in the United States and other countries, including changes in the healthcare payment systems; • results or changes in the status of, or developments relating to, applications for regulatory approvals or clearances for the OCS or competing products; • our announcements or our competitors' announcements of new products, procedures or therapies; • departure of key personnel; • litigation involving us or that may be perceived as having an adverse effect on our business; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • market conditions in the medical device and biotechnology sectors; • changes in general economic, industry and market conditions and trends; • investors' general perception of us; and • sales of large blocks of our stock. The market for medical device and biotechnology companies, in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management' s attention and resources from our business. If securities or industry analysts issue an adverse or misleading opinion regarding our business or do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model or our stock performance, or if our operating results fail to meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline. We have adopted anti- takeover provisions in our restated articles of organization and amended and restated bylaws and are subject to provisions of Massachusetts law that may frustrate any attempt to remove or replace our current board of directors or to effect a change of control or other business combination involving our company. Our restated articles or organization and amended and restated bylaws and certain provisions of Massachusetts law may discourage certain types of transactions involving an actual or potential change of control

of our company that might be beneficial to us or our security holders. For example, our amended and restated bylaws grant the chairperson presiding over any meetings of shareholders the right to adjourn such meeting. Our board of directors also may issue shares of any class or series of preferred stock in the future without shareholder approval and upon such terms as our board of directors may determine. The rights of the holders of our common stock will be subject to, and may be harmed by, the rights of the holders of any class or series of preferred stock that may be issued in the future. Massachusetts state law also prohibits us from engaging in specified business combinations unless the combination is approved or consummated in a prescribed manner. These provisions, alone or together, could delay hostile takeovers and changes in control of our company or changes in our management. Our restated articles of organization designate the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts (or, if and only if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts lacks jurisdiction, another state or federal court located within the Commonwealth of Massachusetts) as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could discourage lawsuits against us and our directors and officers. Our restated articles of organization designate the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts (or, if and only if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts lacks jurisdiction, another state or federal court located within the Commonwealth of Massachusetts) as the sole and exclusive forum for any action under Massachusetts statutory or common law: brought derivatively on our behalf, asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, asserting a claim arising pursuant to any provision of the Massachusetts Business Corporation Act or asserting a claim governed by the internal affairs doctrine, in all cases subject to the court' s having personal jurisdiction over the indispensable parties named as defendants. In addition, our restated articles of organization provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. This provision will not apply to actions arising under the Exchange Act, or the Securities Act of 1933, as amended, or the Securities Act. Additionally, this exclusive forum provision may limit the ability of our shareholders to bring a claim in a judicial forum that such shareholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers. Alternatively, if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts or a court outside of Massachusetts were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other venues or jurisdictions, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, as amended, our management is required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weakness identified by our management in our internal control over financial reporting. In addition, we are required to comply with the SEC' s rules implementing Section 302 of the Sarbanes- Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports, and we are required to disclose significant changes made in our internal controls and procedures on a quarterly basis. If we identify a material weakness in our internal control over financial reporting, we may not be able to remediate the material weakness identified in a timely manner or maintain all of the controls necessary to remain in compliance with our reporting obligations. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting in future periods, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected. Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial condition and results of operations. Accounting principles and related pronouncements, implementation guidelines and interpretations we apply to a wide range of matters that are relevant to our business, including, but not limited to, revenue recognition, leases and stock- based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in accounting pronouncements or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change our reported or expected financial performance. ~~57~~